My Father has has many of these symptoms caused by these poisonous medications!

Acetaminophen Side Effects (for pain. Source Drugs.com)

Causes Autism
Get emergency medical help if you have **signs of an allergic reaction to acetaminophen:** hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

In rare cases, acetaminophen may cause a severe skin reaction that can be fatal, even if you took acetaminophen in the past and had no reaction. **Stop taking this medicine and call your doctor right away if you have skin redness or a rash that spreads and causes blistering and peeling.**

Stop taking acetaminophen and call your doctor at once if you have signs of liver problems:

- stomach pain (upper right side);
- loss of appetite;
- tiredness, itching;
- dark urine, clay-colored stools; or
- jaundice (yellowing of the skin or eyes).

Serious side effects of Acetaminophen

Along with its needed effects, acetaminophen may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking acetaminophen:

Rare

- Bloody or black, tarry stools
- bloody or cloudy urine
- fever with or without chills (not present before treatment and not caused by the condition being treated)
- pain in the lower back and/or side (severe and/or sharp)

- pinpoint red spots on the skin
- skin rash, hives, or itching
- sore throat (not present before treatment and not caused by the condition being treated)
- sores, ulcers, or white spots on the lips or in the mouth
- sudden decrease in the amount of urine
- unusual bleeding or bruising
- unusual tiredness or weakness
- yellow eyes or skin

Symptoms of overdose

- Diarrhea
- increased sweating
- loss of appetite
- nausea or vomiting
- stomach cramps or pain
- swelling, pain, or tenderness in the upper abdomen or stomach area

For Healthcare Professionals

Applies to acetaminophen: **compounding powder, intravenous solution, oral capsule, oral granule effervescent, oral liquid, oral powder, oral powder for reconstitution, oral suspension, oral tablet, oral tablet chewable, oral tablet disintegrating, oral tablet extended release, rectal suppository**.

General

In general, acetaminophen is well-tolerated when administered in therapeutic doses. The most commonly reported adverse reactions have included nausea, vomiting, constipation. Injection site pain and injection site reaction have been reported with the IV product.[Ref]

Hepatic

Common (1% to 10%): Increased aspartate aminotransferase

Rare (less than 0.1%): Increased hepatic transaminases

Frequency not reported: Liver failure[Ref]

Gastrointestinal

Very common (10% or more): Nausea (up to 34%), Vomiting (up to 15%)

Common (1% to 10%): Abdominal pain, diarrhea, constipation, dyspepsia, enlarged abdomen

Frequency not reported: Dry mouth[Ref]

Hypersensitivity

Postmarketing reports: Anaphylaxis, hypersensitivity reactions[Ref]

Hematologic

Common (1% to 10%): Anemia, postoperative hemorrhage

Very rare (less than 0.01%): Thrombocytopenia, leucopenia, neutropenia[Ref]

Dermatologic

Common (1% to 10%): Rash, pruritus

Rare (less than 0.1%): Serious skin reactions such as acute generalized exanthematous pustulosis, Stevens-Johnson syndrome, and toxic epidermal necrolysis

Very rare (less than 0.01%): Pemphigoid reaction, pustular rash, Lyell syndrome[Ref]

Respiratory

Common (1% to 10%): Dyspnea, abnormal breath sounds, pulmonary edema, hypoxia, pleural effusion, stridor, wheezing, coughing[Ref]

Cardiovascular

Common (1% to 10%): Peripheral edema, hypertension, hypotension, tachycardia, chest pain[Ref]

Metabolic

Common (1% to 10%): Hypokalemia, hyperglycemia[Ref]

Nervous system

Common (1% to 10%): Headache, dizziness

Frequency not reported: Dystonia

Musculoskeletal

Common (1% to 10%): Muscle spasms, trismus

Psychiatric

Common (1% to 10%): Insomnia, anxiety

Genitourinary

Common (1% to 10%): Oliguria

Local

Common (1% to 10%): Infusion site pain, injection site reactions

Ocular

Common (1% to 10%): Periorbital edema

Other

Common (1% to 10%): Pyrexia, fatigue

Rare (0.01% to 0.1%): Malaise

Albuterol/ipratropium soln, inhl Side Effects (**for COPD. Source Drugs.com) used to help control the symptoms of lung diseases, such as asthma, chronic bronchitis, and emphysema. It is also used to treat air flow blockage and prevent the worsening of chronic obstructive pulmonary disease (COPD) in patients who need another medicine.**

Serious side effects

Along with its needed effects, albuterol/ipratropium may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking albuterol / ipratropium:

More common

- Body aches or pain
- chills
- cough
- cough producing mucus
- difficulty with breathing
- ear congestion

- fever
- headache
- loss of voice
- runny nose
- sneezing
- sore throat
- stuffy nose
- tightness in the chest
- unusual tiredness or weakness

Less common

- Bladder pain
- bloody or cloudy urine
- blurred vision
- burning while urinating burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- chest pain
- congestion
- diarrhea
- difficult, burning, or painful urination
- dizziness
- fainting
- fast, slow, irregular, pounding, or racing heartbeat or pulse
- frequent urge to urinate
- general feeling of discomfort or illness
- hoarseness
- increased sputum
- joint pain
- loss of appetite
- lower back or side pain
- muscle aches and pains
- nausea
- nervousness
- noisy breathing
- pain
- pain or tenderness around the eyes and cheekbones
- pounding in the ears
- shakiness in the legs, arms, hands, or feet
- shivering
- sweating
- swelling
- tender, swollen glands in the neck

- trembling or shaking of the hands or feet
- trouble sleeping
- trouble swallowing
- voice changes
- vomiting

Rare

- Skin rash or hives
- swelling of the face, lips, eyelids, mouth, or throat

Incidence not known

- Chest discomfort
- decrease in the frequency of urination
- decrease in urine volume
- difficulty in passing urine (dribbling)
- itching skin
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs
- pain or discomfort in the arms, jaw, back, or neck
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- redness of the skin
- welts

Other side effects

Some side effects of albuterol / ipratropium may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

Less common

- Acid or sour stomach
- bad, unusual, or unpleasant (after) taste
- belching
- change in taste
- diarrhea
- difficulty with moving
- dry mouth
- heartburn

- indigestion
- muscle pain or stiffness
- stomach discomfort, upset, or pain
- voice changes

Incidence not known

- Bigger, dilated, or enlarged pupils (black part of the eye)
- blindness
- change in near or distance vision
- decreased vision
- difficulty in focusing eyes
- dry throat
- eye pain
- increased sensitivity of the eyes to light
- itching, redness, tearing, or other sign of eye irritation not present before use of this medicine or becoming worse during use
- lack or loss of strength
- noisy breathing
- redness of the white part of the eyes or inside of the eyelids
- swelling of the eye
- swelling or inflammation of the mouth
- tearing

For Healthcare Professionals

Applies to albuterol / ipratropium: **inhalation aerosol, inhalation solution**.

Respiratory

Common (1% to 10%): Cough, dyspnea, bronchitis, nasopharyngitis, upper respiratory infection, pharyngolaryngeal pain, wheezing, respiratory disorder, sinusitis, bronchospasm, dysphonia, increased sputum

Rare (less than 0.1%): Laryngospasm

Postmarketing reports: Throat irritation, paradoxical bronchospasm, nasal congestion, pharyngeal edema[Ref]

Nervous system

Common (1% to 10%): Headache, dizziness, tremor, nervousness, insomnia

Postmarketing reports: Central nervous system stimulation, mental disorder[Ref]

Other

Common (1% to 10%): Asthenia, influenza -like illness, chest discomfort[Ref]

Cardiovascular

Common (1% to 10%): Hypertension, palpitations, tachycardia, arrhythmia, angina, systolic blood pressured increased

Rare (less than 0.1%): Diastolic blood pressure decreased

Postmarketing reports: Myocardial ischemia, supraventricular tachycardia and/or atrial fibrillation[Ref]

Hypersensitivity

Postmarketing reports: Rash, pruritus, and urticaria (including giant urticaria), angioedema including that of tongue, lips and face, laryngospasm, and anaphylactic reaction[Ref]

Ocular

Common (1% to 10%): Eye pain

Postmarketing reports: Glaucoma, blurred vision, mydriasis, conjunctival hyperemia, halo vision, accommodation disorder, ocular irritation, corneal edema, intraocular pressure increased[Ref]

There are numerous case reports in the literature of precipitation of glaucoma with the use of ipratropium and albuterol via nebulized solution. This is thought to occur through direct contact with the eyes, and is seen with the combination since both beta agonists and anticholinergics can increase intraocular pressure. There is one report of glaucoma associated with the use of nebulized albuterol and ipratropium aerosol in an emergency department. Caution is warranted when the combination is used in patients predisposed to glaucoma. Extra care should be taken to avoid contact with the eyes.[Ref]

Gastrointestinal

Common (1% to 10%): Diarrhea, nausea, dry mouth, constipation, vomiting, dyspepsia, taste perversion, dry throat

Postmarketing reports: Gastrointestinal motility disorder (e.g., diarrhea), drying of secretions, stomatitis, mouth edema[Ref]

Musculoskeletal

Common (1% to 10%): Muscle spasms, myalgia, arthralgia

Postmarketing reports: Muscular weakness[Ref]

Metabolic

Common (1% to 10%): Hypokalemia

Frequency not reported: Lactic acidosis[Ref]

Dermatologic

Common (1% to 10%): Pruritus, rash

Postmarketing reports: Angioedema, hyperhidrosis, skin reaction[Ref]

Genitourinary

Common (1% to 10%): Urinary tract infection, dysuria

Postmarketing reports: Urinary retention

Ascorbic acid Side Effects (Source Drugs.com)

* Diarrhea

- dizziness or faintness (with the injection only)
- flushing or redness of skin
- headache
- increase in urination (mild)
- nausea or vomiting
- stomach cramps

For Healthcare Professionals

Applies to ascorbic acid: **compounding powder, injectable solution, intravenous solution, oral capsule, oral capsule extended release, oral gum, oral liquid, oral tablet, oral tablet chewable, oral tablet disintegrating, oral tablet extended release**.

Renal

Renal side effects have included oxalate and urate kidney stones.[Ref]

Hyperoxaluria appears to be dose-related.[Ref]

Nervous system

Nervous system side effects have included dizziness, faintness, fatigue, and headache in less than 1% of patients. Migraine headache has also been reported. [Ref]

Migraine headache has been reported with a daily dose of 6 grams.

The manufacturer reports temporary dizziness and faintness may be associated with too rapid of a rate during intravenous administration.[Ref]

Other

Other side effects have included flank pain in less than 1% of patients. Conditional scurvy has also been reported.[Ref]

Conditional scurvy is reported to occur following excessive doses of ascorbic acid over a prolonged period of time. The mechanism of action for this condition is thought to be that large doses of ascorbic acid condition the patient over time for rapid clearance of ascorbic acid resulting in scurvy. The plasma levels of ascorbic acid appear to remain within normal limits. The actual existence of conditional scurvy remains controversial.[Ref]

Gastrointestinal

Gastrointestinal side effects have included nausea, diarrhea, abdominal cramps, and esophagitis.[Ref]

Nausea, diarrhea, and abdominal cramps appears to be associated with doses exceeding 2 g per day, although there have been some reports with as little as 1 g per day.

Esophagitis appears to be associated with prolonged or increased contact of ascorbic acid tablets with the esophageal mucosa.[Ref]

Hematologic

Hematologic side effects have included hemolysis.[Ref]

The majority of hemolysis reports have been associated with patients who have concurrent glucose-6-phosphate dehydrogenase deficiency.[Ref]

Local

Local side effects have included transient mild soreness at the site of injection. [Ref]

Bisacodyl Side Effects (Source Drugs.com)

General

ENEMA: The most commonly reported side effects included abdominal discomfort, faintness, mild cramps, and rectal burning.

SUPPOSITORY: The most commonly reported side effects included abdominal discomfort, faintness, mild cramps, and rectal burning.

TABLET: The most commonly reported side effects included cramps, faintness, and stomach discomfort.[Ref]

Gastrointestinal

ENEMA:

Rare (0.01% to 0.1%): Vomiting

Frequency not reported: Abdominal discomfort, abdominal pain, colic, cramping, diarrhea, epigastralgia, nausea, proctitis, mild cramps, tenesmus

SUPPOSITORY:

Common (1% to 10%): Abdominal cramps, abdominal pain, diarrhea, nausea

Uncommon (0.1% to 1%): Abdominal discomfort, blood in stool/hematochezia, vomiting

Rare (0.01% to 0.1%): Colitis, ischemic colitis

Frequency not reported: Abdominal spasm, atonic, nonfunctioning colon, defecation, diarrhea with excessive water and electrolyte loss, mild cramps, proctitis

For Healthcare Professionals

Applies to bisacodyl: **compounding powder, oral delayed release tablet, oral tablet, rectal enema, rectal suppository**.

General

ENEMA: The most commonly reported side effects included abdominal discomfort, faintness, mild cramps, and rectal burning.

SUPPOSITORY: The most commonly reported side effects included abdominal discomfort, faintness, mild cramps, and rectal burning.

TABLET: The most commonly reported side effects included cramps, faintness, and stomach discomfort.[Ref]

Gastrointestinal

ENEMA:

Rare (0.01% to 0.1%): Vomiting

Frequency not reported: Abdominal discomfort, abdominal pain, colic, cramping, diarrhea, epigastralgia, nausea, proctitis, mild cramps, tenesmus

SUPPOSITORY:

Common (1% to 10%): Abdominal cramps, abdominal pain, diarrhea, nausea

Uncommon (0.1% to 1%): Abdominal discomfort, blood in stool/hematochezia, vomiting

Rare (0.01% to 0.1%): Colitis, ischemic colitis

Frequency not reported: Abdominal spasm, atonic, nonfunctioning colon, defecation, diarrhea with excessive water and electrolyte loss, mild cramps, proctitis

TABLET:

Common (1% to 10%): Abdominal cramps, abdominal pain, diarrhea, nausea

Uncommon (0.1% to 1%): Abdominal discomfort, anorectal discomfort, blood in stool/ hematochezia, vomiting

Rare (0.01% to 0.1%): Colitis, ischemic colitis

Frequency not reported: Abdominal spasm, colic, cramps/cramping, defecation, epigastralgia, proctitis, stomach discomfort, tenesmus[Ref]

Prolonged use of this drug may result in diarrhea with excessive water and electrolyte loss, especially potassium.

Colic was treated with atropine derivatives.[Ref]

Nervous system

ENEMA:

Frequency not reported: Faintness, syncope

SUPPOSITORY:

Uncommon (0.1% to 1%): Dizziness

Rare (0.01% to 0.1%): Syncope

Frequency not reported: Faintness, vasovagal response

TABLET:

Uncommon (0.1% to 1%): Dizziness

Rare (0.01% to 0.1%): Syncope

Frequency not reported: Faintness, vasovagal response[Ref]

Local

ENEMA:

Frequency not reported: Local rectal irritation, rectal burning

SUPPOSITORY:

Uncommon (0.1% to 1%): Anorectal discomfort, rectal irritation

Frequency not reported: Rectal burning[Ref]

Hypersensitivity

ENEMA:

Rare (0.01% to 0.1%): Anaphylactoid reactions, angioedema, hypersensitivity reactions

SUPPOSITORY:

Rare (0.01% to 0.1%): Anaphylactic reactions, angioedema, hypersensitivity

TABLET:

Rare (0.01% to 0.1%): Anaphylactic reactions, anaphylactoid reactions, angioedema, hypersensitivity reactions/hypersensitivity[Ref]

Dermatologic

ENEMA:

Rare (0.01% to 0.1%): Mild, transient skin reactions

SUPPOSITORY:

Frequency not reported: Sloughing of the epithelium

TABLET:

Rare (0.01% to 0.1%): Mild, transient skin reactions[Ref]

Metabolic

SUPPOSITORY:

Rare (0.01% to 0.1%): Dehydration

TABLET:

Rare (0.01% to 0.1%): Dehydration[Ref]

Immunologic

ENEMA:

Frequency not reported: Slight indisposition

TABLET:

Frequency not reported: Slight indisposition

Ciprofloxacin Side Effects (Source Drugs.com)

Warning

Oral route (Tablet; Tablet, Extended Release; Suspension)

Fluoroquinolones, including ciprofloxacin, are associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including tendinitis and tendon rupture, peripheral neuropathy, and CNS effects. Discontinue ciprofloxacin and avoid use of fluoroquinolones in patients with these serious adverse reactions. Reserve use of ciprofloxacin for patients with no alternative treatment options for an uncomplicated UTI. Fluoroquinolones, including ciprofloxacin, may exacerbate muscle weakness in persons with myasthenia gravis. Avoid in patients with known history of myasthenia gravis.

Oral route (Suspension; Tablet, Extended Release; Tablet)

Fluoroquinolones, including ciprofloxacin, are associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including tendinitis and tendon rupture, peripheral neuropathy, and CNS effects. Discontinue ciprofloxacin and avoid use of fluoroquinolones in patients with these serious adverse reactions. Reserve use of ciprofloxacin for patients with no alternative treatment options for an acute exacerbation of chronic bronchitis or acute sinusitis. Fluoroquinolones, including ciprofloxacin hydrochloride, may exacerbate muscle weakness in persons with myasthenia gravis. Avoid in patients with known history of myasthenia gravis.

More common

- Diarrhea

Rare

- Bloody or black, tarry stools
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- changes in skin color
- changes in urination
- chest pain, discomfort, tightness, or heaviness
- chills
- clumsiness or unsteadiness
- confusion
- continuing ringing or buzzing or other unexplained noise in the ears
- coughing or spitting up blood
- dizziness, fainting, or lightheadedness when getting up suddenly from a lying or sitting position
- fast, irregular, pounding, or racing heartbeat or pulse
- fever
- headache, severe and throbbing
- hearing loss
- hives or welts, skin rash
- joint stiffness
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or genitals
- light-colored stools
- muscle pain or stiffness
- nausea
- nightmares
- numbness of the hands
- pain in the joints
- pain or discomfort in the arms, jaw, back, or neck
- painful, red lumps under the skin, mostly on the legs
- pounding in the ears
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- redness of the face, neck, arms, and occasionally, upper chest
- seizures
- severe stomach pain, cramping, or burning
- shakiness in the legs, arms, hands, or feet
- swelling of the face, feet, or lower legs
- swollen, painful, or tender lymph glands in the neck, armpit, or groin

- thick, white vaginal discharge with no odor or with a mild odor
- unsteadiness, trembling, or other problems with muscle control or coordination
- unusual drowsiness, dullness, tiredness, weakness, or feeling of sluggishness
- vomiting
- white patches in the mouth or on the tongue
- yellow eyes or skin

Incidence not known

- Blistering, peeling, or loosening of the skin
- bluish-colored lips, fingernails, or palms
- bone pain
- diarrhea, watery and severe, which may also be bloody
- difficulty with breathing, chewing, or talking
- double vision
- excessive muscle tone
- feeling of discomfort
- feeling, seeing, or hearing things that are not there
- increased sensitivity of the skin to sunlight
- increased sensitivity to pain or touch
- irregular or slow heart rate
- loss of sense of smell
- mood changes
- nosebleeds
- rapid heart rate
- red skin lesions, often with a purple center
- seeing, hearing, or feeling things that are not there
- sensation of skin burning
- severe sunburn
- sores, ulcers, or white spots on the lips or in the mouth
- uncontrolled eye movements
- unusual bleeding or bruising
- unusual excitement, nervousness, or restlessness
- vaginal yeast infection

Other side effects of Ciprofloxacin

Some side effects of ciprofloxacin may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

Less common

- Runny or stuffy nose
- sneezing

For Healthcare Professionals

Applies to ciprofloxacin: **intravenous solution, oral powder for reconstitution, oral tablet, oral tablet extended release**.

General

The most common side effects (from clinical trials of all formulations, doses, durations of therapy, and indications) were nausea, diarrhea, abnormal liver function tests, vomiting, and rash. The most common side effects reported with the IV formulation were nausea, diarrhea, vomiting, injection and infusion site reactions, rash, and increased transaminases (transient).[Ref]

Gastrointestinal

Common (1% to 10%): Nausea, diarrhea, vomiting, dyspepsia

Uncommon (0.1% to 1%): Abdominal pains/discomfort, gastrointestinal (GI) pains, flatulence

Rare (0.01% to 0.1%): Elevated amylase, antibiotic-associated colitis, pancreatitis

Frequency not reported: Clostridium difficile-associated diarrhea, constipation, GI bleeding, ileus, intestinal perforation, dry mouth, oral ulceration, epigastric pain, dysphagia, elevated lipase, painful oral mucosa, heartburn, acid reflux, aggravated irritable bowel syndrome, lower abdominal pain

Postmarketing reports: GI candidiasis, oral candidiasis, pseudomembranous colitis[Ref]

Antibiotic-associated colitis with possible fatal outcome was reported very rarely.

The onset of pseudomembranous colitis symptoms has been reported during or after antimicrobial treatment.[Ref]

Dermatologic

Photosensitivity was seen most often when patients were exposed to intense sun (e.g., as when used to treat or prevent travelers' diarrhea).

A 27-year-old woman with mild systemic erythematosus developed toxic epidermal necrolysis (TEN) after starting a second oral course of this drug after a prior 5-day course. She developed a rash, high fever, and diarrhea after taking the 2nd dose and presented with diffuse rash, epidermal sloughing of 60% of the skin, desquamation of the lips, shock, and respiratory distress. She died on the 28th hospital day of TEN, right ventricular failure, and acute respiratory distress syndrome. As of 2003, 9 cases of TEN, including 5 fatalities, had been reported in the literature.

Erythema nodosum, Stevens-Johnson syndrome (potentially life-threatening), and TEN (potentially life-threatening) have also been reported during postmarketing experience.[Ref]

Common (1% to 10%): Rash

Uncommon (0.1% to 1%): Pruritus, urticaria

Rare (0.01% to 0.1%): Angioedema, photosensitivity reactions, sweating/hyperhidrosis, petechiae, blistering

Very rare (less than 0.01%): Erythema multiforme, erythema nodosum, Stevens-Johnson syndrome (potentially life-threatening), toxic epidermal necrolysis (potentially life-threatening)

Frequency not reported: Exfoliative dermatitis, purpura, burning, phototoxicity reaction, dry skin, maculopapular rash, skin disorder, vesiculobullous rash, erythema, hyperpigmentation, cutaneous candidiasis, bullous pemphigoid, vesicles, lobular panniculitis, photoinduced acute exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms (DRESS)

Postmarketing reports: Acute generalized exanthematous pustulosis, fixed eruption[Ref]

Nervous system

Common (1% to 10%): Headache, dizziness/lightheadedness, central nervous system disturbance

Uncommon (0.1% to 1%): Sleep disorders, taste disorders, seizures (including status epilepticus), dysesthesia, paresthesia, vertigo, hearing loss

Rare (0.01% to 0.1%): Syncope, hypoesthesia, tremor, tinnitus, migraine, olfactory nerve disorders, smell disorders, hearing impaired

Very rare (less than 0.01%): Disturbed coordination, intracranial hypertension, benign intracranial hypertension/pseudotumor cerebri, exacerbation of myasthenia gravis, hyperesthesia

Frequency not reported: Unresponsiveness, ataxia, hypertonia, anosmia, nystagmus, taste perversion/bad taste, somnolence/drowsiness, incoordination, disturbance in attention, dyskinesia, myasthenia gravis, paresis, aseptic meningitis, cerebral thrombosis, grand mal convulsion, dysphasia, lethargy, sensory axonal polyneuropathy, sensorimotor axonal polyneuropathy

Postmarketing reports: Taste loss, peripheral neuropathy (may be irreversible), polyneuropathy[Ref]

Seizures have been reported in 2 patients given this drug and foscarnet. The temporal association between the onset of seizures and drug administration suggests a possible drug interaction; causal relationship was not established in either case. Both drugs are individually epileptogenic; concurrent use may potentiate risk of seizures.

Cases of sensory or sensorimotor axonal polyneuropathy (affecting small and/or large axons) resulting in paresthesias, hypoesthesias, dysesthesias, and weakness have been reported.

One survey reported 11 cases of peripheral neuropathy associated with this drug. The severity ranged from mild and reversible to severe and persistent. In 1 case, a 44-year-old female developed numbness, allodynia, hypoesthesia, tremors, electrical and diffuse burning sensations, twitching, disorientation, visual impairment, nausea, temperature intolerance, rash, and palpitations; she remained disabled after 29 months.

Nystagmus, anosmia, hyperesthesia, hypoesthesia, hypertonia, intracranial hypertension, and exacerbation of myasthenia gravis have also been reported during postmarketing experience.[Ref]

Hematologic

Common (1% to 10%): Eosinophilia

Uncommon (0.1% to 1%): Thrombocytopenia, thrombocythemia

Rare (0.01% to 0.1%): Leukopenia, anemia, neutropenia, leukocytosis, pancytopenia, bone marrow depression, abnormal prothrombin level

Very rare (less than 0.01%): Hemolytic anemia, agranulocytosis

Frequency not reported: Decreased hematocrit, decreased platelet counts, increased platelet counts, prolonged prothrombin time, decreased prothrombin, bleeding diathesis, decreased hemoglobin, decreased leukocyte count, increased atypical lymphocyte count, immature WBCs, increased blood monocytes, elevated sedimentation rate, elevated eosinophil counts, lymphadenopathy

Postmarketing reports: Methemoglobinemia, increased INR, prothrombin time prolonged or decreased[Ref]

Pancytopenia (life-threatening or fatal outcome) and bone marrow depression (life-threatening) were reported very rarely; also reported during postmarketing experience.

Increased INR was reported in patients treated with vitamin K antagonists.[Ref]

Hepatic

Common (1% to 10%): Abnormal liver function tests, increased transaminases

Uncommon (0.1% to 1%): Elevated bilirubin, hepatic impairment, cholestatic icterus/cholestatic jaundice, jaundice

Rare (0.01% to 0.1%): Hepatitis, liver necrosis

Very rare (less than 0.01%): Hepatic failure

Frequency not reported: Elevated AST, elevated ALT, elevated GGT[Ref]

Liver necrosis very rarely progressed to life-threatening hepatic failure. Liver necrosis and hepatic failure (including fatal cases) have also been reported during postmarketing experience.[Ref]

Psychiatric

Depression and psychotic reactions (both potentially culminating in self-injurious behavior such as suicidal ideations/thoughts and attempted or completed suicide) have been reported.

Agitation, confusion, and toxic psychosis have also been reported during postmarketing experience.[Ref]

Common (1% to 10%): Restlessness

Uncommon (0.1% to 1%): Psychomotor hyperactivity/agitation, confusion, disorientation, hallucinations

Rare (0.01% to 0.1%): Anxiety reaction, abnormal dreams, depression, psychotic reactions

Frequency not reported: Depersonalization, insomnia, manic reaction, nightmares, paranoia, phobia, toxic psychosis, nervousness, self-injurious behavior, suicidal ideations/thoughts, attempted suicide, completed suicide, catatonia, mania (including hypomania)

Postmarketing reports: Delirium[Ref]

Genitourinary

Common (1% to 10%): Vaginal candidiasis

Rare (0.01% to 0.1%): Hematuria, crystalluria

Frequency not reported: Albuminuria, cylindruria, frequent urination, hemorrhagic cystitis, vaginitis, dysmenorrhea, candiduria, polyuria, urethral bleeding, urinary retention, urinary tract infection, fungal vaginosis, bacterial vaginitis, dysuria, abnormal urine odor, female genital pruritus, vaginal infection, urinary frequency, micturition urgency, vaginal pruritus[Ref]

Crystalluria has been reported in patients with alkaline urine and did not necessarily lead to nephrotoxicity. At physiological urinary pH, the risk of crystalluria was considered minor.

Vaginal candidiasis has also been reported during postmarketing experience.[Ref]

Local

Local IV site reactions occurred more often if the infusion time was 30 minutes or less. These reactions have appeared as local skin reactions and resolved quickly when infusion was completed.

Injection site irritation and induration have been reported with IV infusion time 30 minutes or less (instead of the recommended 1 hour) or when a small vein in the back of the hand was used.[Ref]

Common (1% to 10%): Local IV site reactions, injection and infusion site reactions (e.g., phlebitis, thrombophlebitis)

Frequency not reported: Injection site irritation and induration with IV infusion[Ref]

Musculoskeletal

Arthropathy has primarily been a concern in pediatric patients; however, at least 1 case was described in an adult cystic fibrosis patient receiving this drug. Although cystic fibrosis arthropathy and hypertrophic pulmonary osteoarthropathy typically occur in 7% to 8% of cystic fibrosis adults and adolescents, the arthropathy exhibited in this patient did not resemble either. Several elements in its presentation strongly supported the diagnosis of ciprofloxacin-induced arthropathy, such as: a consistent time of onset with other reported cases of suspected quinolone-induced arthropathy (usually 3 weeks after starting therapy); a lack of history of arthralgia in the patient; reoccurrence upon rechallenge; and resolution of symptoms upon discontinuation of therapy (usually 2 weeks after therapy stopped).

Tendinitis with subsequent tendon rupture has been documented in numerous case reports. One patient with chronic renal failure developed bilateral Achilles tendon rupture after 4 days of ciprofloxacin therapy. Although renal transplant patients and those with end-stage renal disease tend to have an increased risk of Achilles tendinitis and rupture over the general population, quinolone use has been shown to further increase that risk (12% in quinolone-treated patients versus 7% in nonquinolone-treated patients).

As of October 1994, 25 cases of Achilles tendon rupture had been reported to the US FDA. Some ruptures have also occurred in the hand or shoulder. Other risk factors identified included age and corticosteroid use.

There had been 23 reports of tendinitis submitted to the Australian Adverse Drug Reactions Committee (ADRAC) between 2006 and 2008, including reports of Achilles tendinitis, tendon rupture, and tendon pain and swelling. The reports were primarily in male patients (15 cases) older than 56 years who used this drug for 2 to 14 days. In 19 of the reported cases, a fluoroquinolone (generally ciprofloxacin) was the primary suspect; however, details of concomitant serious medical conditions were not documented in most of the reports.

Musculoskeletal side effects reported in pediatric patients included arthralgia, abnormal gait, abnormal joint exam, joint sprains, leg pain, back pain, arthrosis, bone pain, pain, myalgia, arm pain, and decreased range of motion in a joint (knee, elbow, ankle, hip, wrist, shoulder).

Myalgia, tendinitis, and tendon rupture have also been reported during postmarketing experience.[Ref]

Uncommon (0.1% to 1%): Musculoskeletal pain (e.g., extremity pain, back pain, chest pain), arthralgia

Rare (0.01% to 0.1%): Myalgia, arthritis, increased muscle tone and cramping, tendon rupture (mainly Achilles tendon)

Very rare (less than 0.01%): Tendinitis, muscular weakness

Frequency not reported: Arthropathy (including suspected reversible cases), joint stiffness, elevated serum creatine phosphokinase, abnormal joint exam, joint sprains, arthrosis, bone pain, decreased range of motion in a joint (knee, elbow, ankle, hip, wrist, shoulder), jaw pain, neck pain, gout flare-up, joint swelling, muscle spasms, night cramps, knee inflammation

Postmarketing reports: Myoclonus, myasthenia, twitching[Ref]

Cardiovascular

Uncommon (0.1% to 1%): Tachycardia, vasodilatation, hypotension

Rare (0.01% to 0.1%): Vasculitis

Frequency not reported: Angina pectoris, cardiopulmonary arrest, myocardial infarction, hypertension, palpitation, bradycardia, arrhythmia, atrial flutter, cardiac murmur, cardiovascular collapse, ventricular ectopy, ventricular bigeminy, abdominal aortic bruit, postural hypotension

Postmarketing reports: QT prolongation/ECG QT prolonged, torsade de pointes, ventricular arrhythmia[Ref]

Torsade de pointes was reported mainly in patients with risk factors for QT prolongation.

Vasculitis has also been reported during postmarketing experience.[Ref]

Other

Elevated serum theophylline has been reported in patients receiving theophylline concomitantly.

Gait disturbance and elevated serum potassium have also been reported during postmarketing experience.[Ref]

Uncommon (0.1% to 1%): Candida infections, mycotic superinfections, pain, fever, malaise/feeling unwell, asthenia, edema

Very rare (less than 0.01%): Gait disturbance/abnormal gait

Frequency not reported: Irritability, flushing, thirst, elevated serum calcium, elevated serum potassium, elevated triglycerides, decreased serum albumin, decreased serum potassium, decreased total serum protein, elevated serum theophylline, serum phenytoin altered, chills, swelling, breast pain, achiness, weakness, fatigue, suprapubic pain, rigors, tenderness, fungal infection, increased body temperature

Postmarketing reports: Elevated serum cholesterol[Ref]

Metabolic

Uncommon (0.1% to 1%): Elevated blood alkaline phosphatase, decreased appetite/anorexia, decreased food intake

Rare (0.01% to 0.1%): Hyperglycemia, hypoglycemia

Frequency not reported: Elevated LDH, elevated uric acid, elevated blood glucose, decreased uric acid, decreased blood glucose, acidosis, symptomatic hypoglycemia[Ref]

Quinolone class antibiotics have been associated with symptomatic hypoglycemia.[Ref]

Renal

Allergic interstitial nephritis resulting in nonoliguric renal failure has been described in numerous case reports. Several cases included symptoms of rash, fever, and arthralgia and were accompanied by eosinophilia and eosinophiluria. Cases of allergic interstitial nephritis often responded to short courses of corticosteroid therapy.[Ref]

Uncommon (0.1% to 1%): Renal impairment, renal failure

Rare (0.01% to 0.1%): Tubulointerstitial nephritis

Frequency not reported: Elevated serum creatinine, renal calculi, elevated BUN, decreased BUN, abnormal kidney function, allergic interstitial nephritis, nephritis, myoglobin-associated acute kidney injury/failure[Ref]

Ocular

Uncommon (0.1% to 1%): Visual disturbances (e.g., chromatopsia, diplopia, photopsia)

Very rare (less than 0.01%): Visual color distortions

Frequency not reported: Decreased visual acuity, blurred vision, cataracts, multiple punctate lenticular opacities, eye pain[Ref]

Quinolone class antibiotics have been associated with cataracts and multiple punctate lenticular opacities.[Ref]

Hypersensitivity

Rare (0.01% to 0.1%): Allergic reactions, anaphylactic shock (life-threatening), allergic edema

Very rare (less than 0.01%): Anaphylactic reaction, serum sickness-like reaction

Frequency not reported: Anaphylactoid reactions, necrotizing vasculitis, cutaneous vasculitis[Ref]

Allergic reactions ranged from urticaria to anaphylactic reactions, including life-threatening anaphylactic shock.

At least 2 cases have been reported of patients developing a cutaneous vasculitis related to use of this drug. The vasculitis resolved without medical intervention after the drug was discontinued.

Serum sickness-like reaction and anaphylactic shock (life-threatening) have also been reported during postmarketing experience.[Ref]

Respiratory

Rare (0.01% to 0.1%): Dyspnea (including asthmatic condition)

Frequency not reported: Bronchospasm, hemoptysis, laryngeal edema, respiratory arrest, epistaxis, hiccough, pulmonary edema, pleural effusion, pulmonary embolism, respiratory distress, wheeze, cough, upper respiratory tract infection, pharyngitis, nasopharyngitis[Ref]

Endocrine

Frequency not reported: Gynecomastia[Ref]

Immunologic

Frequency not reported: Jarisch-Herxheimer reaction[Ref]

Oral ciprofloxacin has been associated with a case of Jarisch-Herxheimer reaction (characterized by hypotension, tachycardia, and disseminated intravascular coagulation) in a 14-year-old female with tickborne relapsing fever.

Digoxin Side Effects (Source Drugs.com)

Medically reviewed by Drugs.com. Last updated on Jun 15, 2023.

- Serious side effects
- Other side effects
- Professional info

Applies to digoxin: **oral solution, oral tablet**.

Serious side effects of Digoxin

Along with its needed effects, digoxin may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking digoxin:

More common

- Dizziness
- fainting

- fast, pounding, or irregular heartbeat or pulse
- slow heartbeat

Rare

- Black, tarry stools
- bleeding gums
- blood in the urine or stools
- bloody vomit
- pinpoint red spots on the skin
- rash with flat lesions or small raised lesions on the skin
- severe stomach pain
- unusual bleeding or bruising

Incidence not known

- Chest pain or discomfort
- nausea
- shortness of breath
- sweating
- swelling of the feet and lower legs
- troubled breathing
- unusual tiredness or weakness

Other side effects of Digoxin

Some side effects of digoxin may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

Less common

- Agitation or combativeness
- anxiety
- confusion
- depression
- diarrhea
- expressed fear of impending death
- hallucinations
- rash
- vomiting

Incidence not known

- Blurred or loss of vision
- disturbed color perception
- double vision
- halos around lights
- headache
- lack of feeling or emotion
- loss of appetite
- night blindness
- overbright appearance of lights
- swelling of the breasts or breast soreness in both females and males
- tunnel vision
- weakness
- weight loss

• For Healthcare Professionals

Applies to digoxin: **compounding powder, injectable solution, oral capsule, oral elixir, oral tablet**.

General

Overall incidence of adverse reactions with this drug has been reported to be 5% to 20%, with 15% to 20% of adverse events considered serious. Cardiac toxicity accounts for about one-half, gastrointestinal disturbances for about one-fourth, and CNS and other toxicity for about one-fourth of these adverse events.[Ref]

Cardiovascular

Common (1% to 10%): Arrhythmia, conduction disturbances, bigeminy, trigeminy, PR prolongation, sinus bradycardia

Postmarketing reports: Supraventricular tachyarrhythmia, atrial tachycardia, nodal tachycardia, ventricular arrhythmia, ventricular premature contraction, ST segment depression, atrioventricular block, ventricular fibrillation[Ref]

Gastrointestinal

Common (1% to 10%): Nausea, vomiting, diarrhea, lower stomach pain

Frequency not reported: Intestinal ischemia, intestinal hemorrhagic necrosis[Ref]

Nervous system

Common (1% to 10%): Central nervous system (CNS) disturbances, dizziness, drowsiness, headache[Ref]

Other

Common (1% to 10%): Central nervous system (CNS) disturbances, dizziness, drowsiness, headache[Ref]

Dermatologic

Common (1% to 10%): Skin rashes of urticarial or scarlatiniform character

Frequency not reported: Maculopapular rash[Ref]

Metabolic

Common (1% to 10%): Anorexia or loss of appetite[Ref]

Ocular

Common (1% to 10%): Blurred vision or visual disturbances[Ref]

Psychiatric

Uncommon (0.1% to 1%): Depression

Frequency not reported: Apathy, confusion, anxiety, delirium, hallucination

Postmarketing reports: Psychosis[Ref]

Hematologic

Frequency not reported: Thrombocytopenia

Serious side effects of Diltiazem (Source Drugs.com)

Along with its needed effects, diltiazem may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking diltiazem:

More common

- Body aches or pain
- congestion
- cough
- dryness or soreness of the throat
- fever
- hoarseness
- runny nose
- tender or swollen glands in the neck
- trouble swallowing
- voice changes

Less common

- Chest pain, discomfort, or tightness
- chills
- diarrhea
- difficult or labored breathing
- feeling faint, dizzy, or lightheaded
- feeling of warmth or heat
- flushing or redness of the skin, especially on the face and neck
- general feeling of discomfort or illness
- headache
- joint pain
- loss of appetite
- muscle aches and pains
- nausea
- shivering
- slow or irregular heartbeat
- sweating
- swelling of the hands, ankles, feet, or lower legs
- trouble sleeping
- unusual tiredness or weakness
- vomiting

Incidence not known

- Blistering, peeling, or loosening of the skin
- itching
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs
- no heartbeat
- red skin lesions, often with a purple center

- red, irritated eyes
- sores, ulcers, or white spots in the mouth or on the lips

Other side effects of Diltiazem

Some side effects of diltiazem may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

More common

- Sneezing
- stuffy nose

Less common

- Acid or sour stomach
- belching
- constipation
- continuing ringing or buzzing or other unexplained noise in the ears
- degenerative disease of the joint
- difficulty with moving
- hearing loss
- heartburn
- indigestion
- lack or loss of strength
- muscle aching or cramping
- muscle pains or stiffness
- pain or tenderness around the eyes and cheekbones
- rash
- stomach discomfort, upset, or pain
- swollen joints

Incidence not known

- Loss or thinning of the hair

• For Healthcare Professionals

Applies to diltiazem: **compounding powder, intravenous powder for injection, intravenous solution, oral capsule extended release, oral tablet, oral tablet extended release**.

General

The most commonly reported side effects include edema, headache, and dizziness.[Ref]

Cardiovascular

Very common (10% or more): Peripheral edema (up to 15%)

Common (1% to 10%): Arrhythmia (junctional rhythm/isorhythmic dissociation), asymptomatic/symptomatic hypotension, atrioventricular (AV) block (first/second/third degree), bradycardia, bundle branch block, ECG abnormality, edema, extrasystole/ventricular extrasystole, flushing, lower limb edema, palpitations, vasodilation

Uncommon (0.1% to 1%): Orthostatic hypotension

Frequency not reported: Angina, asystole/cardiac arrest, atrial flutter, chest pain, development/aggravation of congestive heart failure, hypotension, sinoatrial block, sinus node dysfunction, sinus pause/arrest, vasculitis, ventricular arrhythmia, ventricular fibrillation, ventricular tachycardia/tachycardia

Postmarketing reports: Myocardial infarction, vasodilation symptoms (flushing, lower limb edema, sweating)[Ref]

A patient with Prinzmetal's angina developed asystole after a single, 60 mg dose.

Myocardial infarction was not readily distinguishable from the natural history of the disease.

Vasodilatory events (e.g., peripheral edema, headache, flushing) are dose-related and may be more common in elderly patients.

First degree AV block and sinus bradycardia occurred more frequently with higher doses.[Ref]

Other

Common (1% to 10%): Asthenia, fatigue, flu syndrome, infection, malaise, pain

Frequency not reported: Thirst, tinnitus[Ref]

Gastrointestinal

Common (1% to 10%): Abdominal enlargement, constipation, dyspepsia, gastric pain, nausea

Uncommon (0.1% to 1%): Diarrhea, vomiting

Rare (0.01% to 0.1%): Dry mouth

Frequency not reported: Gastrointestinal disorder, gingivitis, gingival hyperplasia[Ref]

Dermatologic

Well-documented cases of rashes (as leukocytoclastic vasculitis) have been reported, but a definitive between these events and this drug have not been established.

Lichenoid keratosis and hyperpigmentation occurred in skin exposed to the sun. [Ref]

Common (1% to 10%): Erythema, hot flushes, rash, urticaria

Frequency not reported: Acute generalized exanthematous pustular dermatitis, desquamative erythema with/without fever exfoliative dermatitis, facial edema, hyperhidrosis/sweating, hyperpigmentation, leukocytoclastic vasculitis, petechiae, photosensitivity (lichenoid keratosis), pruritus, Steven-Johnson's syndrome

Postmarketing reports: Allergic dermatitis, alopecia, angioneurotic edema, erythema multiforme, generalized dermatitis, musculocutaneous reactions, simple erythema, toxic epidermal necrolysis[Ref]

Respiratory

Common (1% to 10%): Bronchitis, cough, increased cough, pharyngitis, sinus/nasal congestion

Frequency not reported: Dyspnea, epistaxis

Postmarketing reports: Asthma aggravation, bronchospasm[Ref]

Nervous system

Dizziness occurred more frequently with higher doses.[Ref]

Common (1% to 10%): Dizziness, headache, lightheadedness

Frequency not reported: Amnesia, dysgeusia, extrapyramidal syndrome/symptoms, gait abnormality, paresthesia, somnolence, syncope, tremor[Ref]

Musculoskeletal

Common (1% to 10%): Myalgia

Frequency not reported: Creatine phosphokinase (CPK) increase, muscle cramp, muscle pain, muscle weakness, myopathy, neck rigidity, osteoarticular pain[Ref]

Metabolic

Common (1% to 10%): Gout

Frequency not reported: Anorexia, hyperglycemia, hyperuricemia, mild elevation of alkaline phosphatase, mild elevation of lactate dehydrogenase, thirst, weight increase[Ref]

Genitourinary

Common (1% to 10%): Impotence

Frequency not reported: Albuminuria, crystalluria, nocturia, polyuria, sexual difficulties[Ref]

Ocular

Common (1% to 10%): Conjunctivitis

Frequency not reported: Amblyopia, eye irritation, periorbital edema, retinopathy[Ref]

Local

Common (1% to 10%): Injection site reactions (e.g., itching, burning)[Ref]

Psychiatric

Uncommon (0.1% to 1%): Insomnia, nervousness

Frequency not reported: Abnormal dreams, depression, hallucinations, mood changes (including depression), personality change[Ref]

Hepatic

There were rare cases of clinical hepatitis that were reversible with discontinuation of this drug.[Ref]

Uncommon (0.1% to 1%): Increased hepatic enzymes (ALT, AST)

Frequency not reported: Clinical hepatitis/hepatitis[Ref]

Hematologic

Frequency not reported: Eosinophilia, hemolytic anemia, increased bleeding time, leukopenia, lymphadenopathy, thrombocytopenia

Postmarketing reports: Purpura[Ref]

Hypersensitivity

Frequency not reported: Allergic reactions, angioedema (including facial/periorbital edema)[Ref]

Endocrine

Frequency not reported: Gynecomastia

Docusate Side Effects

Serious side effects of Docusate

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

Other side effects of Docusate

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Stomach cramps.

• For Healthcare Professionals

Applies to docusate: **compounding powder, oral capsule, oral liquid, oral solution, oral syrup, oral tablet, rectal enema**.

Gastrointestinal

Gastrointestinal side effects have included gastrointestinal cramping. Reports of bitter taste and throat irritation have been reported with administration of primarily the syrup and liquid formulations.[Ref]

Dermatologic

Dermatologic side effects have included rash.[Ref]

Metabolic

Metabolic side effects have included at least one case report of hypomagnesemia.[Ref]

Metabolic abnormalities reported include hypomagnesemia in one woman who took docusate chronically throughout her pregnancy. Magnesium levels returned to normal following discontinuation of docusate.[Ref]

Ferrous sulfate Side Effects

Warning

- Accidental overdose of drugs that have iron in them is a leading cause of deadly poisoning in children younger than 6 years of age. Keep away from children. If this drug is taken by accident, call a doctor or poison control center right away.

Serious side effects of Ferrous sulfate

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Black, tarry, or bloody stools.
- Fever.
- Very upset stomach or throwing up.
- Very bad belly pain.
- Throwing up blood or throw up that looks like coffee grounds.

Other side effects of Ferrous sulfate

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Belly pain.
- Diarrhea.
- Constipation.
- Change in color of stool to green.
- Not hungry.
- Upset stomach or throwing up.
- Stomach cramps.

  These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice

  about side effects.

For Healthcare Professionals

Applies to ferrous sulfate: **compounding powder, oral capsule extended release, oral delayed release tablet, oral elixir, oral liquid, oral syrup, oral tablet, oral tablet extended release**.

Gastrointestinal

Frequency not reported: Nausea, epigastric pain, altered bowel habit (constipation, diarrhea), discolored (blackened) stools, fecal impaction, gastrointestinal irritation, contact irritation resulting in erosion or ulceration, tooth discoloration[Ref]

Hypersensitivity

Frequency not reported: Hypersensitivity reactions (from rashes to anaphylaxis)

Lidocaine Side Effects

Serious side effects of Lidocaine

Along with its needed effects, lidocaine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor or nurse immediately if any of the following side effects occur while taking lidocaine:

Incidence not known

- Bluish-colored lips, fingernails, or palms blurred or double vision
- chest pain or discomfort
- cold, clammy, pale skin
- confusion
- continuing ringing or buzzing or other unexplained noise in the ears
- cough
- dark urine
- difficulty breathing
- difficulty swallowing
- dizziness or lightheadedness
- dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- drowsiness
- fast heartbeat
- fever
- headache
- hearing loss
- hives, itching, skin rash
- irregular heartbeat
- irregular, fast or slow, or shallow breathing
- loss of consciousness
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- rapid or slow heart rate
- seizures
- slow or irregular heartbeat

- sore throat
- sweating
- tightness in the chest
- tremor
- twitching
- unusual bleeding or bruising
- unusual tiredness or weakness

Other side effects of Lidocaine

Some side effects of lidocaine may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

Incidence not known

- Cold or numb feeling
- false or unusual sense of well-being
- feeling of heat
- loss of bladder and bowel control
- loss of genital sensation and sexual function
- nervousness
- vomiting

Serious side effects of Lidocaine

Along with its needed effects, lidocaine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor or nurse immediately if any of the following side effects occur while taking lidocaine:

Incidence not known

- Bluish-colored lips, fingernails, or palms blurred or double vision
- chest pain or discomfort
- cold, clammy, pale skin
- confusion
- continuing ringing or buzzing or other unexplained noise in the ears
- cough

- dark urine
- difficulty breathing
- difficulty swallowing
- dizziness or lightheadedness
- dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- drowsiness
- fast heartbeat
- fever
- headache
- hearing loss
- hives, itching, skin rash
- irregular heartbeat
- irregular, fast or slow, or shallow breathing
- loss of consciousness
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- rapid or slow heart rate
- seizures
- slow or irregular heartbeat
- sore throat
- sweating
- tightness in the chest
- tremor
- twitching
- unusual bleeding or bruising
- unusual tiredness or weakness

Other side effects of Lidocaine

Some side effects of lidocaine may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

Incidence not known

- Cold or numb feeling
- false or unusual sense of well-being
- feeling of heat
- loss of bladder and bowel control

- loss of genital sensation and sexual function
- nervousness
- vomiting

For Healthcare Professionals

Applies to lidocaine: **compounding powder, injectable solution, intravenous solution**.

General

Adverse reactions following administration of this drug are similar in nature to those observed with other amide local anesthetic agents. The most serious adverse reactions tend to be systemic in nature. In general, these adverse reactions are dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption, or inadvertent intravascular injection, or may result from a hypersensitivity, idiosyncrasy, or diminished tolerance on the part of the patient.[Ref]

Cardiovascular

Frequency not reported: Bradycardia, hypotension, cardiovascular collapse, cardiac arrest, circulatory collapse, hypertension, arrhythmia, maternal hypotension, shock, tachycardia, ventricular fibrillation, heart block, myocardial depression, peripheral vasodilation[Ref]

Nervous system

Frequency not reported: Lightheadedness, headache, dizziness, drowsiness, cold/numbness, tremor, convulsions, unconsciousness, positional headache, peripheral nerve symptoms, spinal cord deficit, paresthesia, speech slurred, arachnoiditis, peripheral nerve injury, coma, paralysis of the lower extremities, cauda equina syndrome, Horner's syndrome, hemiparesis, circumoral paresthesia, nystagmus[Ref]

Gastrointestinal

Frequency not reported: Vomiting, nausea, bowel control loss, swallowing difficult, numbness of tongue[Ref]

Psychiatric

Frequency not reported: Nervousness, apprehension, euphoria, confusion, agitation, disorientation, psychosis, restlessness, excitement[Ref]

Hematologic

Frequency not reported: Methemoglobinemia[Ref]

Dermatologic

Frequency not reported: Urticaria, cutaneous lesion, dermatitis, rash, angioedema, face edema[Ref]

Genitourinary

Frequency not reported: Bladder control loss, sexual function loss, perineal sensation loss, urinary retention[Ref]

Immunologic

Frequency not reported: Allergic reaction, anaphylaxis/anaphylactoid reaction[Ref]

Local

Frequency not reported: Persistent anesthesia[Ref]

Metabolic

Frequency not reported: Hypoglycemia[Ref]

Musculoskeletal

Frequency not reported: Twitching, backache, leg pain, buttock pain[Ref]

Ocular

Frequency not reported: Blurred/doubled vision, diplopia, transient amaurosis, bilateral amaurosis[Ref]

Other

Frequency not reported: Tinnitus, feeling hot, edema, shiver, total spinal block, hyperacusis, weakness, sphincter control loss[Ref]

Respiratory

Frequency not reported: Respiratory depression, respiratory arrest, dyspnea, bronchospasm, hypoventilation, apnea, respiratory inadequacy, respiratory failure, yawning

Metoprolol Side Effects

Warning

Oral route (Tablet)

Ischemic Heart DiseaseDo not abruptly discontinue metoprolol tartrate tablets USP therapy in patients with coronary artery disease. Severe exacerbation of angina, myocardial infarction and ventricular arrhythmias have been reported in patients with coronary artery disease following the abrupt discontinuation of therapy with beta-blockers. When discontinuing chronically administered metoprolol tartrate tablets USP, particularly in patients with coronary artery disease, the dosage should be gradually reduced over a period of 1 to 2 weeks and the patient should be carefully monitored. If angina markedly worsens or acute coronary insufficiency develops, metoprolol tartrate tablets USP administration should be reinstated promptly, at least temporarily, and other measures appropriate for the management of unstable angina should be taken. Patients should be warned against interruption or discontinuation of therapy without the physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue metoprolol tartrate tablets USP therapy abruptly even in patients treated only for hypertension.

Serious side effects of Metoprolol

Along with its needed effects, metoprolol may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking metoprolol:

More common

- Blurred vision
- chest pain or discomfort
- confusion
- dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- slow or irregular heartbeat
- sweating
- unusual tiredness or weakness

Less common

- Bloating or swelling of the face, arms, hands, lower legs, or feet
- chest tightness
- cough
- decreased urine output
- difficult or labored breathing
- difficulty with speaking
- dilated neck veins
- disturbed color perception
- double vision
- fast, pounding, or racing heartbeat or pulse
- halos around lights
- headache
- inability to move the arms, legs, or facial muscles
- inability to speak
- irregular breathing
- loss of vision
- night blindness
- noisy breathing
- overbright appearance of lights
- pain, tension, and weakness upon walking that subsides during periods of rest
- paleness or cold feeling in the fingertips and toes
- rapid weight gain
- seeing, hearing, or feeling things that are not there
- short-term memory loss
- slow speech
- swelling of the face, fingers, feet, or lower legs
- tingling of the hands or feet
- tingling or pain in the fingers or toes when exposed to cold temperatures
- trouble breathing
- tunnel vision
- unusual weight gain or loss

Rare

- Bluish color of the skin of the fingers or toes
- chills
- clay-colored stools
- continuing loss of appetite
- continuing or severe abdominal or stomach pain
- continuing or severe nausea and vomiting

- dark urine
- difficulty with moving
- fever
- hoarseness
- increased frequency of urination
- itching skin
- light-colored stools
- lower back or side pain
- muscle pain or stiffness
- numbness of the fingers or toes
- pain, swelling, or redness in the joints
- rash
- sore throat
- sores, ulcers, or white spots on the lips or in the mouth
- unpleasant breath odor
- unusual bleeding or bruising
- upper right abdominal or stomach pain
- vomiting of blood
- weakness
- yellow eyes and skin

Incidence not known

- Black, tarry stools
- bleeding gums
- blood in the urine or stools
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- cool, sweaty skin
- pinpoint red spots on the skin

Get emergency help immediately if any of the following symptoms of overdose occur while taking metoprolol:

Symptoms of overdose

- Bluish color of the fingernails, lips, skin, palms, or nail beds
- change in consciousness
- loss of consciousness
- no blood pressure or pulse
- stopping of the heart
- very drowsy or sleepy

Other side effects of Metoprolol

Some side effects of metoprolol may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

Less common

- Belching
- bloated feeling
- decreased interest in sexual intercourse
- difficulty having a bowel movement
- discouragement
- dry mouth
- excess air or gas in stomach or bowels
- feeling of constant movement of self or surroundings
- feeling of fullness
- feeling of indigestion
- feeling sad or empty
- inability to have or keep an erection
- irritability
- loss in sexual ability, desire, drive, or performance
- loss of interest or pleasure
- nightmares
- pain in the chest below the breastbone
- passing gas
- redness or other discoloration of the skin
- runny or stuffy nose
- sensation of spinning
- sneezing
- tiredness
- trouble concentrating
- trouble sleeping

Rare

- Bone pain
- continuing ringing or buzzing or other unexplained noise in the ears
- dry eyes
- hair loss or thinning of the hair

- hearing loss
- increased sensitivity of the skin to sunlight
- pain in the penis on erection
- severe sunburn

Incidence not known

- Change in taste or bad, unusual, or unpleasant (after) taste
- fear or nervousness
- hives or welts

For Healthcare Professionals

Applies to metoprolol: **compounding powder, injectable solution, oral capsule extended release, oral solution, oral tablet, oral tablet extended release**.

General

The most common adverse reactions were tiredness, dizziness, depression, shortness of breath, bradycardia, hypotension, diarrhea, pruritus, and rash.[Ref]

Cardiovascular

Very common (10% or more): Heart failure (up to 27.5%), hypotension (systolic blood pressure less than 90 mmHg) (up to 27.4%), bradycardia (heart rate less than 40 beats per minute) (up to 15.9%),

Common (1% to 10%): Cold extremities, arterial insufficiency, palpitation, first degree heart block (P-R interval 0.26 seconds or greater), second or third degree heart block, postural disorders

Uncommon (0.1% to 1%): Cardiogenic shock in patients with acute myocardial infarction

Rare (0.01% to 0.1%): Disturbances of cardiac conduction, cardiac arrhythmia

Very rare (less than 0.01%): Intermittent claudication increased

Frequency not reported: Claudication[Ref]

Gastrointestinal

Common (1% to 10%): Diarrhea, nausea, dry mouth, gastric pain, constipation, flatulence, heartburn, abdominal pain, vomiting

Frequency not reported: Retroperitoneal fibrosis[Ref]

Other

Common (1% to 10%): Tiredness, peripheral edema, accident and/or injury, death, fatigue

Uncommon (0.1% to 1%): Edema, precordial pain

Frequency not reported: Lactic dehydrogenase elevated

Postmarketing reports: Chest pain[Ref]

Nervous system

Common (1% to 10%): Dizziness, vertigo, stroke, headache

Uncommon (0.1% to 1%): Paresthesia, somnolence, impaired concentration

Rare (0.01% to 0.1%): Alertness decreased

Very rare (less than 0.01%): Amnesia/memory impairment, tinnitus, taste disturbance

Frequency not reported: Short-term memory loss

Postmarketing reports: Syncope[Ref]

Respiratory

Common (1% to 10%): Shortness of breath, wheezing, dyspnea

Rare (less than 0.1%): Rhinitis[Ref]

Dermatologic

Common (1% to 10%): Pruritus, rash

Uncommon (0.1% to 1%): Sweating increased

Rare (0.01% to 0.1%): Loss of hair

Very rare (less than 0.01%): Photosensitivity reactions, psoriasis aggravated, gangrene in patients with preexisting severe peripheral circulatory disorders, hyperhidrosis, alopecia[Ref]

Psychiatric

Common (1% to 10%): Depression

Uncommon (0.1% to 1%): Insomnia, nightmare

Rare (0.01% to 0.1%): Nervousness, anxiety

Very rare (less than 0.01%): Confusion, hallucination, personality disorder, disturbances of libido

Frequency not reported: Sleep disturbance[Ref]

Musculoskeletal

Uncommon (0.1% to 1%): Muscle cramps

Very rare (less than 0.01%): Arthralgia, arthritis

Frequency not reported: Musculoskeletal pain[Ref]

Metabolic

Uncommon (0.1% to 1%): Weight gain

Frequency not reported: Unstable diabetes

Postmarketing reports: Blood triglycerides increased, high density lipoprotein (HDL) decreased[Ref]

Ocular

Rare (less than 0.1%): Visual disturbance, dry and/or irritated eyes, conjunctivitis

Frequency not reported: Blurred vision[Ref]

Hepatic

Rare (0.01% to 0.1%): Liver function test abnormalities

Very rare (less than 0.01%): Hepatitis

Frequency not reported: Transaminase elevated, alkaline phosphatase elevated

Postmarketing reports: Jaundice, non-specific hepatic dysfunction[Ref]

Genitourinary

Rare (0.01% to 0.1%): Impotence/sexual dysfunction

Very rare (less than 0.01%): Peyronie's disease[Ref]

Immunologic

Rare (less than 0.1%): Positive antinuclear antibodies[Ref]

Hematologic

Very rare (less than 0.01%): Thrombocytopenia

Frequency not reported: Agranulocytosis[Ref]

Miconazole Side Effects

Serious side effects of Miconazole

Along with its needed effects, miconazole may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking miconazole:

Less common

- Body aches or pain
- cough
- difficulty with breathing
- ear congestion
- fever or chills
- headache
- loss of voice
- lower back or side pain
- nasal congestion
- painful or difficult urination
- pale skin
- runny nose
- sneezing
- sore throat
- troubled breathing with exertion
- unusual bleeding or bruising
- unusual tiredness or weakness

Rare

- Black, tarry stools
- pale skin
- shortness of breath
- ulcers, sores, or white spots in the mouth

Other side effects of Miconazole

Some side effects of miconazole may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

More common

- Change in taste
- diarrhea
- dry mouth
- headache
- itching skin
- loss of taste
- nausea
- pain, redness, and swelling of the gums
- sores on the tongue
- toothache

Less common

- Abdominal or stomach pain
- loss of appetite
- pain
- upper abdominal or stomach pain
- weakness

For Healthcare Professionals

Applies to miconazole: **buccal tablet, intravenous solution**.

General

The overall safety of the buccal tablets was assessed in 480 adult subjects, including 315 HIV-infected subjects, 147 subjects with head and neck cancer, and 18 healthy subjects. Discontinuation due to side effects occurred in 0.6% of subjects overall.

The most common side effects reported with the oral gel were nausea, abnormal product taste, vomiting, oral discomfort, regurgitation, dry mouth, and dysgeusia.

Although the IV product has been discontinued in the US, side effects associated with this formulation have been included.[Ref]

Local

Buccal tablets:

-Very common (10% or more): Local side effects (including oral discomfort, oral burning, oral pain, gingival pain, gingival swelling, gingival pruritus, tongue ulceration, mouth ulceration, glossodynia, dry mouth, application site pain/discomfort, toothache, loss of taste, altered taste, tooth disorder)

IV formulation:

-Very common (10% or more): Phlebitis (at least 33%)[Ref]

Local side effects (including oral discomfort, oral burning, oral pain, gingival pain, gingival swelling, gingival pruritus, tongue ulceration, mouth ulceration, glossodynia, dry mouth, application site pain/discomfort, toothache, loss of taste, altered taste) have been reported in 12.1% of HIV-infected patients. Local side effects (including oral discomfort, oral pain, dry mouth, glossodynia, loss of taste, altered taste, tongue ulceration, mouth ulceration, tooth disorder, application site discomfort/pain) have been reported in 9.5% of patients with head and neck cancer.[Ref]

Gastrointestinal

Buccal tablets:

-Common (1% to 10%): Diarrhea, nausea, vomiting, dry mouth, oral discomfort, upper abdominal pain, gastroenteritis

Oral gel:

-Common (1% to 10%): Dry mouth, nausea, oral discomfort, vomiting, regurgitation

-Postmarketing reports: Diarrhea, stomatitis, tongue discoloration

IV formulation:

-Frequency not reported: Nausea, vomiting, anorexia, diarrhea[Ref]

Nervous system

Buccal tablets:

-Common (1% to 10%): Headache, dysgeusia, ageusia

Oral gel:

-Common (1% to 10%): Dysgeusia

IV formulation:

-Frequency not reported: Dizziness[Ref]

Respiratory

Buccal tablets:

-Common (1% to 10%): Cough, upper respiratory infection, pharyngeal pain

Oral gel:

-Postmarketing reports: Choking[Ref]

Hematologic

Buccal tablets:

-Common (1% to 10%): Anemia, lymphopenia

-Uncommon (0.1% to 1%): Neutropenia

Oral gel:

-Frequency not reported: Increase in INR, increase in bleeding events (e.g., epistaxis, contusion, hematuria, melena, hematemesis, hematoma, hemorrhages)

IV formulation:

-Frequency not reported: Transient decreases in hematocrit, thrombocytosis, thrombocytopenia, erythrocyte aggregation[Ref]

Increases in INR and bleeding events (e.g., epistaxis, contusion, hematuria, melena, hematemesis, hematoma, hemorrhages) have been reported in patients treated with oral anticoagulants (e.g., warfarin) and this oral gel; some events had fatal outcomes.[Ref]

Other

Buccal tablets:

-Common (1% to 10%): Fatigue, pain

Oral gel:

-Common (1% to 10%): Abnormal product taste

-Postmarketing reports: Malaise, chills

IV formulation:

-Frequency not reported: Fever, chills[Ref]

Dermatologic

Buccal tablets:

-Common (1% to 10%): Pruritus

Oral gel:

-Postmarketing reports: Angioedema, toxic epidermal necrolysis (Lyell syndrome), Stevens-Johnson syndrome, urticaria, rash, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms

IV formulation:

-Frequency not reported: Pruritus, maculopapular rash[Ref]

Pruritus (which may have been accompanied by maculopapular rash) has been reported with the IV formulation, and in some cases, severe pruritus developed after weeks of therapy or after therapy was completed.[Ref]

Hepatic

Buccal tablets:

-Common (1% to 10%): Elevated GGT

Oral gel:

-Postmarketing reports: Hepatitis[Ref]

Hypersensitivity

Buccal tablets:

-Frequency not reported: Allergic reaction (including anaphylactic reactions, hypersensitivity)

Oral gel:

-Postmarketing reports: Allergic conditions (including angioneurotic edema, anaphylactic reaction), hypersensitivity

IV formulation:

-Frequency not reported: Anaphylaxis, contact dermatitis[Ref]

Contact dermatitis has been reported when the IV formulation was used topically.[Ref]

Metabolic

Increases in cholesterol and triglycerides reported in patients receiving the IV formulation were due to its vehicle (Cremophor EL [polyethoxylated castor oil]), and were reversible upon discontinuation of the drug. Hyperlipidemia due to Cremophor EL had the atypical appearance of gamma-2 globulin.

Hyponatremia associated with the IV formulation resulted in a mean decrease in sodium of 10 mEq/L, but usually was not a reason to discontinue therapy. This drug was usually administered in normal saline solution to help minimize decreases in sodium.[Ref]

Oral gel:

-Postmarketing reports: Anorexia

IV formulation:

-Frequency not reported: Hyperlipidemia, hyponatremia[Ref]

Ocular

Oral gel:

-Postmarketing reports: Accommodation difficulty

IV formulation:

-Frequency not reported: Blurred vision

Cardiovascular

Cardiac arrhythmias, tachycardia, and cardiac arrest may have been associated with rapid infusion of the drug and due to the Cremophor EL vehicle.[Ref]

IV formulation:

-Frequency not reported: Cardiac arrhythmias, tachycardia, cardiac arrest[Ref]

Psychiatric

IV formulation:

-Frequency not reported: Euphoria

Renal

IV formulation:

-Frequency not reported: Acute renal failure[Ref]

Acute renal failure, possibly due to the IV formulation, was reported in 1 patient with a renal allograft.[Ref]

Mirtazapine Side Effects

Warning

Oral route (Tablet; Tablet, Disintegrating)

Suicidal Thoughts and BehaviorsIncreased risk of suicidal thoughts and behavior in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. Mirtazapine is not approved for use in pediatric patients..

Serious side effects of Mirtazapine

Along with its needed effects, mirtazapine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking mirtazapine:

Less common

- Decreased or increased movement
- mood or mental changes, including abnormal thinking, agitation, anxiety, confusion, and feelings of not caring
- skin rash
- swelling
- trouble breathing

Rare

- Change in menstrual cycle (periods)
- chills
- decreased sexual ability
- fever
- menstrual pain
- mood or mental changes, including anger, feelings of being outside the body, mood swings, and unusual excitement
- mouth sores
- seeing, hearing, or feeling things that are not there

- seizures
- sore throat

Incidence not known

- Black, tarry stools
- blistering, peeling, loosening of skin
- chest pain
- fainting
- hives, itching, skin rash
- irregular or slow heart rate
- joint or muscle pain
- painful or difficult urination
- red, irritated eyes
- red skin lesions, often with a purple center
- sore throat
- sores, ulcers, or white spots on the lips or in the mouth
- swollen glands
- unusual bleeding or bruising
- unusual tiredness or weakness

Other side effects of Mirtazapine

Some side effects of mirtazapine may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

More common

- Constipation
- dizziness
- drowsiness
- dry mouth
- increased appetite
- weight gain

Less common

- Abnormal dreams
- back pain

- dizziness or fainting when getting up suddenly from a lying or sitting position
- increased need to urinate
- increased sensitivity to touch
- increased thirst
- low blood pressure
- muscle pain
- nausea
- sense of constant movement of self or surroundings
- stomach pain
- trembling or shaking
- vomiting

Incidence not known

- Painful or prolonged erection of the penis
- swelling of the breasts or unusual milk production

For Healthcare Professionals

Applies to mirtazapine: **oral tablet, oral tablet disintegrating**.

Nervous system

Very common (10% or more): Somnolence (up to 54%)

Common (1% to 10%): Dizziness, tremor, headache, sedation/drowsiness

Uncommon (0.1% to 1%): Hypesthesia, hypokinesia, vertigo, amnesia, hyperkinesia, paresthesia, lethargy

Rare (0.01% to 0.1%): Syncope, migraine, ataxia, dyskinesia, extrapyramidal syndrome, coordination abnormal, dysarthria, dystonia, reflexes increased, restless legs, akathisia (psychomotor restlessness)

Very rare (less than 0.01%): Vascular headache, cerebral ischemia, aphasia, nystagmus, stupor, dementia, paralysis, grand mal convulsion, hypotonia, taste loss, myoclonus, parosmia

Frequency not reported: Hypertonia, taste perversion, convulsions (insults)

Postmarketing reports: Impaired concentration, cerebrovascular disorder, movement disorders[Ref]

Gastrointestinal

Very common (10% or more): Dry mouth (up to 25%), constipation (up to 13%)

Common (1% to 10%): Nausea

Uncommon (0.1% to 1%): Abdominal pain, abdominal syndrome acute, vomiting, diarrhea

Rare (0.01% to 0.1%): Abdomen enlarged, eructation, glossitis, nausea and vomiting, gum hemorrhage, stomatitis, colitis, oral hypoesthesia

Very rare (less than 0.01%): Tongue discoloration, ulcerative stomatitis, salivary gland enlargement, increased salivation, intestinal obstruction, pancreatitis, aphthous stomatitis, gastritis, gastroenteritis, oral moniliasis, tongue edema

Frequency not reported: Dyspepsia, flatulence, oral paresthesia, mouth edema[Ref]

Metabolic

Very common (10% or more): Increased appetite (up to 17%), weight gain (up to 12%)

Uncommon (0.1% to 1%): Anorexia

Rare (0.01% to 0.1%): Dehydration, weight loss

Very rare (less than 0.01%): Gout, acid phosphatase increased, diabetes mellitus, hyponatremia

Frequency not reported: Hypertriglyceridemia

Postmarketing reports: Hypercholesterolemia, hyperlipidemia[Ref]

Psychiatric

Common (1% to 10%): Abnormal dreams, thinking abnormal, confusion

Uncommon (0.1% to 1%): Apathy, depression, agitation, anxiety, insomnia

Rare (0.01% to 0.1%): Delirium, delusions, depersonalization, increased libido, hallucinations, manic reaction/mania, neurosis, hostility, emotional lability, euphoria, paranoid reaction, nightmares/vivid dreams

Very rare (less than 0.01%): Drug dependence, psychotic depression, withdrawal syndrome, serotonin syndrome, aggression

Frequency not reported: Nervousness, decreased libido, suicidal ideation, suicidal behavior, somnambulism

Postmarketing reports: Psychomotor restlessness, drug withdrawal symptoms, paroniria[Ref]

Cardiovascular

Common (1% to 10%): Peripheral edema, edema

Uncommon (0.1% to 1%): Hypertension, vasodilation, orthostatic hypotension

Rare (0.01% to 0.1%): Angina pectoris, myocardial infarction, bradycardia, ventricular extrasystoles, hypotension

Very rare (less than 0.01%): Chest pain substernal, atrial arrhythmia, bigeminy, cardiomegaly, phlebitis, left heart failure

Frequency not reported: Chest pain, palpitation, tachycardia, postural hypotension, ECG changes

Postmarketing reports: Ventricular arrhythmia, Torsades de pointes, generalized edema, localized edema[Ref]

There was a mean increase in heart rate observed in patients given this drug compared to placebo (3.4 bpm versus 0.8 bpm, respectively); however, the clinical significance of this difference is unknown.[Ref]

Musculoskeletal

Common (1% to 10%): Back pain, myalgia

Uncommon (0.1% to 1%): Myasthenia, arthralgia, twitching

Rare (0.01% to 0.1%): Neck rigidity, neck pain, arthritis, tenosynovitis

Very rare (less than 0.01%): Pathologic fracture, osteoporosis fracture, bone pain, myositis, tendon rupture, arthrosis, bursitis

Postmarketing reports: Increased creatine kinase blood levels, rhabdomyolysis[Ref]

Respiratory

Common (1% to 10%): Dyspnea

Uncommon (0.1% to 1%): Cough increased, sinusitis

Rare (0.01% to 0.1%): Epistaxis, bronchitis, asthma, pneumonia

Very rare (less than 0.01%): Respiratory/pulmonary embolus, asphyxia, laryngitis, pneumothorax, hiccup

Frequency not reported: Pharyngitis, rhinitis

Postmarketing reports: Pulmonary embolism[Ref]

Genitourinary

Common (1% to 10%): Urinary frequency

Uncommon (0.1% to 1%): Urinary tract infection

Rare (0.01% to 0.1%): Dysuria, urinary incontinence, urinary retention, vaginitis, hematuria, breast pain, amenorrhea, dysmenorrhea, leukorrhea, impotence

Very rare (less than 0.01%): Polyuria, urethritis, metrorrhagia, abnormal ejaculation, breast engorgement, breast enlargement, urinary urgency, menorrhagia[Ref]

Other

Common (1% to 10%): Asthenia

Uncommon (0.1% to 1%): Malaise, thirst, fatigue

Rare (0.01% to 0.1%): Chills, fever, face edema, ulcer, ear pain, deafness, hyperacusis

Very rare (less than 0.01%): Healing abnormal, partial transitory deafness, otitis media

Frequency not reported: Pain, tinnitus[Ref]

Immunologic

Common (1% to 10%): Influenza/flu syndrome

Frequency not reported: Infection[Ref]

Dermatologic

Uncommon (0.1% to 1%): Pruritus, rash, exanthema

Rare (0.01% to 0.1%): Photosensitivity reaction, acne, exfoliative dermatitis, dry skin, herpes simplex, alopecia

Very rare (less than 0.01%): Cellulitis, petechia, urticaria, herpes zoster, skin hypertrophy, skin ulcer, seborrhea

Frequency not reported: Sweating

Postmarketing reports: Stevens-Johnson Syndrome, bullous dermatitis, erythema multiforme, toxic epidermal necrolysis, rash (including erythematous and maculopapular)[Ref]

Ocular

Rare (0.01% to 0.1%): Eye pain, abnormality of accommodation, conjunctivitis, keratoconjunctivitis, lacrimation disorder, angle-closure glaucoma

Very rare (less than 0.01%): Diplopia, blepharitis

Frequency not reported: Amblyopia

Postmarketing reports: Glaucoma[Ref]

Hepatic

Rare (0.01% to 0.1%): Cholecystitis, liver function tests abnormal

Very rare (less than 0.01%): Cirrhosis of the liver, AST increased, ALT increased

Postmarketing reports: Jaundice, hepatitis[Ref]

Renal

Rare (0.01% to 0.1%): Kidney calculus, cystitis[Ref]

Hematologic

Very rare (less than 0.01%): Lymphadenopathy, leukopenia, anemia, thrombocytopenia, lymphocytosis, pancytopenia

Frequency not reported: Bone marrow depression (granulocytopenia, agranulocytosis, aplastic anemia, thrombocytopenia), eosinophilia

Postmarketing reports: Thromboembolic disorder, coagulation disorder[Ref]

Endocrine

Very rare (less than 0.01%): Goiter, hypothyroidism

Frequency not reported: Inappropriate antidiuretic hormone secretion[Ref]

Oxycodone Side Effects

Warning

Oral route (Capsule, Extended Release)

Addiction, Abuse, and MisuseOxycodone extended-release (ER) exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing oxycodone ER, and monitor all patients regularly for the development of these

behaviors or conditions.Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse and misuse, the Food and Drug Administration (FDA) has required a REMS for these products. Under the requirements of the REMS, drug companies with approved opioid analgesic products must make REMS-compliant education programs available to healthcare providers. Healthcare providers are strongly encouraged to: complete a REMS-compliant education program, counsel patients and/or their caregivers, with every prescription, on safe use, serious risks, storage, and disposal of these products, emphasize to patients and their caregivers the importance of reading the Medication Guide every time it is provided by their pharmacists, and consider other tools to improve patient, household, and community safety.Life-Threatening Respiratory DepressionSerious, life-threatening, or fatal respiratory depression may occur with use of oxycodone ER. Monitor for respiratory depression, especially during initiation of oxycodone ER or following a dose increase.Accidental IngestionAccidental ingestion of even one dose of oxycodone ER, especially by children, can result in a fatal overdose of oxycodone ER.Neonatal Opioid Withdrawal SyndromeProlonged use of oxycodone ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.Cytochrome P450 3A4 InteractionThe concomitant use of oxycodone ER with all cytochrome P450 3A4 inhibitors may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse reactions and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in oxycodone plasma concentration. Monitor patients receiving oxycodone ER and any CYP3A4 inhibitor or inducer.Risks from Concomitant Use with Benzodiazepines or Other CNS DepressantsReserve concomitant prescribing of oxycodone ER and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

Oral route (Tablet; Tablet, Extended Release)

Addiction, abuse, and misuse, leading to overdose and death has been reported. Before prescribing, assess the patient's risk and watch for signs of the development of these behaviors. To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy

(REMS) for these products. Serious and fatal respiratory depression may occur. Monitor for respiratory depression, especially when beginning treatment or increasing dose. Advise patients to swallow tablets whole to avoid overdose. Accidental ingestion can result in a fatal overdose, especially in children. Prolonged use in pregnancy may lead to life-threatening neonatal withdrawal syndrome. If oxycodone hydrochloride must be used during pregnancy, advise the patient of the risk and ensure that treatment will be available to the infant. Initiation of CYP3A4 inhibitors or discontinuation of CYP3A4 inducers can cause a fatal oxycodone hydrochloride overdose. Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for patients with inadequate alternative treatment options. Limit dosages and durations to the minimum required and follow patients for signs and symptoms of respiratory depression and sedation.

Oral route (Solution)

Use caution when prescribing and administering oxycodone oral solution as dosing errors due to mg and mL could result in accidental overdose and death. Ensure the proper dose is indicated and dispensed. Oxycodone oral solution should be kept out of the reach of children. Seek emergency help immediately if accidental ingestion occurs.

Serious side effects of Oxycodone

Along with its needed effects, oxycodone may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking oxycodone:

Less common

- Chills
- cold sweats
- confusion
- difficult or labored breathing
- dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- fever
- tightness in the chest
- twitching

Rare

- Bloating or swelling of the face, arms, hands, lower legs, or feet
- blood in the urine
- burning while urinating burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- chest pain
- cough
- decrease in the frequency of urination
- decreased urine output
- difficult or painful urination
- difficulty in passing urine (dribbling)
- difficulty with swallowing
- dizziness
- dry mouth
- fainting
- fast, irregular, pounding, or racing heartbeat or pulse
- feeling of warmth or heat
- flushing or redness of the skin, especially on the face and neck
- frequent urination
- headache
- hives, itching, or skin rash
- increase in heart rate
- increased thirst
- increased volume of pale, dilute urine
- lightheadedness
- muscle pain or cramps
- nausea
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- rapid breathing
- rapid weight gain
- seizures
- severe constipation
- severe vomiting
- stomach pain
- sunken eyes
- sweating
- swollen, painful, or tender lymph glands in the neck, armpit, or groin
- thirst
- trembling or shaking of the hands or feet
- unusual tiredness or weakness
- unusual weight gain or loss

- vomiting
- wrinkled skin

Incidence not known

- Blurred vision
- choking
- clay-colored stools
- cold, clammy skin
- dark urine
- darkening of the skin
- diarrhea
- fast, weak pulse
- gagging
- irregular, fast, slow, or shallow breathing
- loss of appetite
- loss of consciousness
- pale or blue lips, fingernails, or skin
- unpleasant breath odor
- very slow heartbeat
- yellow eyes or skin

Get emergency help immediately if any of the following symptoms of overdose occur while taking oxycodone:

Symptoms of overdose

- Change in consciousness
- chest pain or discomfort
- cold, clammy skin
- constricted, pinpoint, or small pupils (black part of the eye)
- coughing that sometimes produces a pink frothy sputum
- decreased awareness or responsiveness
- increased sweating
- irregular, fast, or slow, or shallow breathing
- loss of consciousness
- no muscle tone or movement
- pale or blue lips, fingernails, or skin
- sleepiness or unusual drowsiness
- slow or irregular heartbeat
- swelling in the legs and ankles,

Other side effects of Oxycodone

Some side effects of oxycodone may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

More common

- Difficulty having a bowel movement
- drowsiness
- lack or loss of strength
- relaxed and calm feeling

Less common

- Abnormal dreams
- anxiety
- belching
- burning feeling in the chest or stomach
- false or unusual sense of well-being
- heartburn
- hiccups
- indigestion
- stomach discomfort or upset
- tenderness in the stomach area
- trouble sleeping
- weight loss

Rare

- Absent, missed, or irregular menstrual periods
- bad, unusual or unpleasant (after) taste
- bloated or full feeling
- body aches or pain
- change in taste
- change in walking and balance
- changes in vision
- clumsiness or unsteadiness
- continuous ringing or buzzing or other unexplained noise in the ears
- crying
- decreased interest in sexual intercourse

- deep or fast breathing with dizziness
- delusions of persecution, mistrust, suspiciousness, or combativeness
- dental caries or tooth decay
- depression
- difficulty with speaking
- dry skin
- dryness or soreness of the throat
- excess air or gas in the stomach or bowels
- excessive muscle tone
- feeling of constant movement of self or surroundings
- feeling of unreality
- general feeling of discomfort or illness
- headache, severe and throbbing
- hearing loss
- hoarseness
- inability to have or keep an erection
- increase in body movements
- increased appetite
- increased cough
- irritability
- loss in sexual ability, desire, drive, or performance
- loss of heat from the body
- loss of memory
- loss of strength or energy
- muscle stiffness, tension, tightness, pain, or weakness
- neck pain
- numbness of the feet, hands, and around the mouth
- passing of gas
- problems with memory
- quick to react or overreact emotionally
- rapidly changing moods
- red, swollen skin
- restlessness
- runny nose
- scaly skin
- sensation of spinning
- sense of detachment from self or body
- swelling or inflammation of the mouth
- voice changes

For Healthcare Professionals

Applies to oxycodone: **compounding powder, oral capsule, oral capsule extended release, oral concentrate, oral solution, oral tablet, oral tablet extended release**.

General

The most commonly reported adverse reactions in adults included constipation, nausea, somnolence, dizziness, vomiting, pruritus, headache, dry mouth, asthenia, and sweating. In pediatric patients, the most frequently observed adverse reactions included vomiting, nausea, headache, pyrexia, and constipation.[Ref]

Nervous system

Very common (10% or more): Headache (14%, pediatrics)

Common (1% to 10%): Dizziness (pediatrics)

Frequency not reported: Confusion, hypertonia, hypesthesia, nervousness, neuralgia, personality disorder, tremor, migraine

Postmarketing reports: Serotonin syndrome, hyperalgesia, allodynia[Ref]

Respiratory

Frequency not reported: Apnea, respiratory arrest, bronchitis, cough increased, dyspnea, epistaxis, laryngismus, lung disorder, pharyngitis, rhinitis, sinusitis[Ref]

Severe adverse effects such as respiratory depression can be treated with the opioid antagonist naloxone.[Ref]

Gastrointestinal

Very common (10% or more): Nausea (23% to 27%), constipation (23% to 26%), vomiting (12% to 14%)

Frequency not reported: Abdominal pain, anorexia, diarrhea, dyspepsia, dysphagia, gingivitis, glossitis[Ref]

In pediatric studies with the oral extended release product, gastrointestinal adverse events were reported in 40% of patients 11 to 16 years of age (56 of 140); vomiting, nausea, constipation, and diarrhea were experienced by 21%, 15%, 9%, and 6%, respectively. Abdominal pain and gastroesophageal reflux disease were reported in 1% to less than 5% of patients.[Ref]

Psychiatric

Frequency not reported: Paranoia, psychosis, hallucinations, agitation, anxiety[Ref]

Dermatologic

Common (1% to 10%): Pruritus, hyperhidrosis, rash

Frequency not reported: Herpes simplex, rash, sweating, urticaria[Ref]

Hepatic

Frequency not reported: Increased hepatic enzymes

Cardiovascular

Frequency not reported: QTc prolongation at higher doses, deep thrombophlebitis, heart failure, hemorrhage, hypotension, palpitation, tachycardia, edema, peripheral edema, vasodilation, circulatory collapse[Ref]

Genitourinary

Common (1% to 10%): Dysuria, urinary retention

Frequency not reported: Urinary tract infection[Ref]

Hypersensitivity

Frequency not reported: Allergic reaction

Postmarketing reports: Anaphylaxis[Ref]

Immunologic

Frequency not reported: Flu syndrome, infection, sepsis[Ref]

Metabolic

Common (1% to 10%): Decreased appetite (pediatrics)

Frequency not reported: Gout, hyperglycemia, iron deficiency anemia

Postmarketing reports: Hypoglycemia[Ref]

Musculoskeletal

Frequency not reported: Back pain, neck pain, arthralgia, arthritis, bone pain, myalgia, pathological fracture[Ref]

Ocular

Frequency not reported: Photosensitivity reaction, amblyopia[Ref]

Other

Very common (10% or more): Pyrexia (11%, pediatrics)

Frequency not reported: Chills and fever, accidental injury[Ref]

Endocrine

Opioids:

Postmarketing reports: Adrenal insufficiency, androgen deficiency[Ref]

Pantoprazole Side Effects

Serious side effects of Pantoprazole

Along with its needed effects, pantoprazole may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking pantoprazole:

Less common

- Blurred vision
- dry mouth
- flushed, dry skin
- fruit-like breath odor
- increased hunger
- increased thirst
- increased urination
- nausea
- stomach pain
- sweating
- trouble breathing
- unexplained weight loss
- vomiting

Incidence not known

- Absence of or decrease in body movements

- black, tarry stools
- blindness
- blistering, peeling, or loosening of the skin
- bloating
- bloody or cloudy urine
- bloody, black, or tarry stools
- blurred vision
- chest pain or tightness
- chills
- clay-colored stools
- confusion
- constipation
- continuous ringing or buzzing or other unexplained noise in the ears
- cough
- dark urine
- decreased vision
- diarrhea
- difficulty with speaking
- difficulty with swallowing
- dizziness or lightheadedness
- drowsiness
- fast heartbeat
- feeling of constant movement of self or surroundings
- fever
- greatly decreased frequency of urination or amount of urine
- headache
- hearing loss
- high fever
- hives, itching, or skin rash
- indigestion
- joint pain
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or genitals
- light-colored stools
- loss of appetite
- mood or mental changes
- muscle cramp, pain, stiffness, spasms, or twitching
- muscle cramps in the hands, arms, feet, legs, or face
- numbness and tingling around the mouth, fingertips, or feet
- painful or difficult urination
- pains in the stomach, side, or abdomen, possibly radiating to the back
- pale skin

- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- red skin lesions, often with a purple center
- red, irritated eyes
- seizures
- sensation of spinning
- sore throat
- sores, ulcers, or white spots on the lips or in the mouth
- stomach pain, continuing
- swelling of the feet or lower legs
- swollen glands
- trembling
- unexplained bleeding or bruising
- unpleasant breath odor
- unusual tiredness or weakness
- vomiting of blood
- yellow eyes or skin

Other side effects of Pantoprazole

Some side effects of pantoprazole may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

Less common

- Belching
- bloated or full feeling
- excess air or gas in the stomach or bowels
- passing gas
- trouble sleeping

Incidence not known

- Decreased interest in sexual intercourse
- inability to have or keep an erection
- increased watering of the mouth
- loss in sexual ability, desire, drive, or performance

For Healthcare Professionals

Applies to pantoprazole: **intravenous powder for injection, intravenous solution, oral delayed release tablet, oral granule enteric coated, oral suspension**.

General

The most commonly reported side effects were headache, diarrhea, and injection site thrombophlebitis (in IV formulations).[Ref]

Nervous system

Very common (10% or more): Headache (Up to 26.4%), taste pervasion (Up to 18.2%)

Common (1% to 10%): Dizziness, metallic/bitter taste, somnolence

Rare (0.01% to 0.1%): Taste disorders

Very rare (less than 0.01%): Change to the sense of taste, reduced movement, speech disorder

Frequency not reported: Paresthesia, vertigo

Postmarketing reports: Ageusia, dysgeusia[Ref]

Headache was a very commonly reported side effect in pediatric patients 2 to 16 years of age. In adults, headache occurred most frequently in patients given quadruple therapy (pantoprazole, bismuth, metronidazole, tetracycline) for H pylori infections, but was also very common in triple therapy (pantoprazole, amoxicillin, clarithromycin).

Taste pervasion most frequently occurred in patients given triple therapy, but it was also very common in patients given quadruple therapy.[Ref]

Respiratory

Nasopharyngitis and pharyngolaryngeal pain occurred in pediatric patients between the ages of 2 to 16 years.[Ref]

Very common (10% or more): Nasopharyngitis (up to 13.6%), pharyngolaryngeal pain (up to 13.2%)

Common (1% to 10%): Cough, nasal congestion, pharyngitis

Very rare (less than 0.01%): Change to the sense of smell, dyspnea

Frequency not reported: Upper respiratory tract infection[Ref]

Gastrointestinal

Very common (10% or more): Diarrhea (Up to 11.6%)

Common (1% to 10%): Abdominal pain, benign fundic gland polyps/fundic gland polyps, buccal inflammation, constipation, dry mouth, dyspepsia, fecal discoloration, flatulence, heartburn, nausea, oral moniliasis, pruritus ani, tongue discoloration, tongue pain, upper abdominal pain, vomiting

Uncommon (0.1% to 1%): Abdominal discomfort/distention, bloating, loose stools

Rare (0.01% to 0.1%): Colon polyp, rectal disorder

Very rare (less than 0.01%): Increased saliva

Frequency not reported: Clostridium difficile-associated diarrhea, severe eructation[Ref]

Diarrhea occurred most frequently in patients given quadruple therapy (pantoprazole, bismuth, metronidazole, tetracycline) for Helicobacter pylori infections, but was also very common in triple therapy (pantoprazole, amoxicillin, clarithromycin).

Nausea, vomiting, abdominal pain, dry mouth, and constipation were more commonly reported in patients given triple therapy, compared to patients given quadruple therapy.

Fecal and/or tongue discoloration occurred more commonly in patients given quadruple therapy versus patients given triple therapy.[Ref]

Other

Common (1% to 10%): Tiredness

Uncommon (0.1% to 1%): Asthenia, fatigue, malaise

Rare (0.01% to 0.1%): Body temperature increased, fever

Very rare (less than 0.01%): Pain, tinnitus

Frequency not reported: Facial edema[Ref]

Psychiatric

Confusion, depression, hallucinations, and disorientation, especially in predisposed patients, occurred with use, and was aggravated in patients with preexisting conditions.[Ref]

Common (1% to 10%): Depression (and all aggravations)

Uncommon (0.1% to 1%): Sleep disorders

Rare (0.01% to 0.1%): Confusion (and all aggravations), disorientation (and all aggravations), hallucination (and all aggravations)

Very rare (less than 0.01%): Anxiety

Postmarketing reports: Insomnia[Ref]

Hepatic

Common (1% to 10%): Increased liver enzymes (transaminases, GGT)

Rare (0.01% to 0.1%): Increased bilirubin

Very rare (less than 0.01%): Cholestatic hepatitis, hepatitis, hepatocellular failure, jaundice

Frequency not reported: Hepatic effects, hepatocellular injury, liver function tests abnormal

Postmarketing reports: Hepatocellular damage[Ref]

Severe hepatocellular damage leading to jaundice/hepatic failure is predicted to have a frequency of 1 in 1,000,000 patients.[Ref]

Dermatologic

Common (1% to 10%): Exanthema/exanthemata, rash

Uncommon (0.1% to 1%): Eruption, increased sweating, pruritus

Rare (0.01% to 0.1%): Urticaria

Very rare (less than 0.01%): Erythema multiforme, flushing, Lyell syndrome, photosensitivity/photosensitivity reaction, severe skin reactions, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN)

Frequency not reported: Cutaneous lupus erythematosus, facial edema, fatal skin reactions, fatal TEN, subacute cutaneous lupus erythematosus[Ref]

Cardiovascular

Common (1% to 10%): Chest pain

Rare (0.01% to 0.1%): Hypertension, peripheral edema, thrombophlebitis

Very rare (less than 0.01%): Circulatory collapse, flushing, hot flushes, substernal chest pain

Frequency not reported: Generalized edema[Ref]

Musculoskeletal

Common (1% to 10%): Arthralgia

Uncommon (0.1% to 1%): Fracture of the hip/wrist/spine

Rare (0.01% to 0.1%): Myalgia

Very rare (less than 0.01%): Skeletal pain

Frequency not reported: Bone fracture, elevated creatine phosphokinase (CPK)/elevated creatine kinase (CK), muscle spasm, systemic lupus erythematosus

Postmarketing reports: Rhabdomyolysis[Ref]

Muscle spasm occurred as a consequence of electrolyte disturbances.[Ref]

Metabolic

Hypocalcemia occurred in association with hypomagnesemia.

Anorexia commonly occurred in patients with H pylori.[Ref]

Common (1% to 10%): Anorexia

Rare (0.01% to 0.1%): Hyperlipidemia, increased cholesterol, increased triglycerides, lipid increases, weight changes

Frequency not reported: Cyanocobalamin (vitamin B12) deficiency), electrolyte disturbances, hypocalcemia, hypokalemia, hypomagnesemia, hyponatremia, potential for exacerbation of zinc deficiency[Ref]

Local

Common (1% to 10%): Injection site thrombophlebitis

Frequency not reported: Injection site reactions[Ref]

Immunologic

Common (1% to 10%): Influenza-like symptoms, moniliasis

Rare (0.01% to 0.1%): Sepsis[Ref]

Hypersensitivity

Rare (0.01% to 0.1%): Anaphylactic reactions, anaphylactic shock, angioedema/Quincke's edema, hypersensitivity, hypersensitivity reactions

Frequency not reported: Allergic reactions

Postmarketing reports: Anaphylaxis[Ref]

Hematologic

Rare (0.01% to 0.1%): Agranulocytosis, anemia

Very rare (less than 0.01%): Increased coagulation time, leukopenia, pancytopenia, thrombocytopenia[Ref]

Ocular

Uncommon (0.1% to 1%): Blurred vision, visual disturbances

Very rare (less than 0.01%): Conjunctivitis[Ref]

Endocrine

Rare (0.01% to 0.1%): Gynecomastia[Ref]

Renal

Very rare (less than 0.01%): Interstitial nephritis (with possible progression to renal failure)

Frequency not reported: Acute interstitial nephritis[Ref]

Polyethylene glycol 3350 Side Effects: Common, Severe, Long Term Also known as PEG

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

More common

1. Full or bloated feeling
2. pain in the upper stomach
3. pressure in the stomach
4. stomach pain
5. swelling of the stomach area
6. vomiting

Rare

1. Confusion
2. decreased urine output
3. dizziness
4. dry mouth
5. fast or irregular heartbeat
6. headache
7. increased thirst
8. loss of appetite
9. loss of consciousness
10. muscle pain or cramps
11. numbness or tingling in the hands, feet, fingertips, lips, or mouth
12. seizures
13. swelling of the face, ankles, or hands
14. unusual tiredness or weakness

Incidence not known

1. Blistering, crusting, irritation, itching, or reddening of the skin
2. bloating or swelling of the face, arms, hands, lower legs, or feet
3. bloody or black, tarry stools
4. bloody urine
5. blue lips and fingernails
6. blurred vision
7. chest pain or tightness
8. chills
9. constipation
10. cough
11. coughing that sometimes produces a pink frothy sputum
12. cracked, dry, scaly skin
13. difficult, fast, noisy breathing
14. difficulty swallowing
15. fainting
16. fast, pounding, or irregular heartbeat or pulse

17. fever
18. heartburn
19. hives, itching, skin rash
20. increase in heart rate
21. increased sweating
22. lightheadedness
23. lower back or side pain
24. nausea
25. nervousness
26. pale skin
27. pounding in the ears
28. puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
29. rapid breathing
30. rapid weight gain
31. runny nose
32. severe stomach pain
33. slow heartbeat
34. sunken eyes
35. swelling of the neck
36. thirst
37. throat tightness
38. tingling of the hands or feet
39. tremor
40. trouble breathing
41. unusual weight gain or loss
42. vomiting of blood or material that looks like coffee grounds
43. wrinkled skin

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

1. Burning, itching, or pain around the anus
2. difficulty with sleeping
3. feeling unusually cold
4. general feeling of discomfort or illness
5. hunger

6. shivering

Less common

1. Belching
2. indigestion
3. stomach discomfort or upset

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Bisacodyl / polyethylene glycol 3350 / potassium chloride / sodium bicarbonate / sodium chloride Side Effects

Warning

Use only as directed. Tell your doctor if you use other medicines or have other medical conditions or allergies.

no bowel movement within 6 hours after use;

- severe nausea, severe stomach pain or bloating;
- rectal bleeding;
- irregular heartbeats;
- headache, confusion, or a seizure;
- dehydration symptoms--feeling very thirsty or hot, being unable to urinate, heavy sweating, or hot and dry skin; or
- signs of an electrolyte imbalance--increased thirst or urination, constipation, muscle pain or weakness, leg cramps, numbness or tingling, feeling jittery, irregular heartbeats, fluttering in your chest, or a choking feeling.

Tell your doctor right away if you have trouble drinking clear liquid.

Common side effects may include:

- feeling full or uncomfortable;
- stomach cramps;
- nausea, vomiting; or
- bloating.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

For Healthcare Professionals

Applies to bisacodyl/polyethylene glycol 3350/potassium chloride/sodium bicarbonate/sodium chloride: **oral kit**.

Gastrointestinal

Gastrointestinal side effects have been reported the most frequently. These have included nausea (17.1%), cramping (9.1%), abdominal fullness (22.3%), vomiting (5.9%) and overall discomfort (19.1%).

A small percentage of patients who received PEG-ELS have reportedly experienced Mallory-Weiss tears of the esophagus and esophageal perforation. In addition, at least one case of rectal prolapse has been reported.[Ref]

Mallory-Weiss tears are quite rare with administration of PEG-ELS. In one study it occurred in only 0.06% of over 3,000 patients.

Complete rectal prolapse was reported in a 71-year-old who had been given 4 L of PEG-ELS. The patient was observed for 2 days and had no recurrence of the prolapse.

During administration of PEG-ELS (4 liters) two deaths occurred in patients with end-stage renal failure following the development of vomiting, diarrhea and dysnatremia.[Ref]

Dermatologic

Dermatologic side effects reported with PEG-ELS have rarely included urticaria and dermatitis.[Ref]

Cardiovascular

Cardiovascular side effects of PEG-ELS have included arrhythmias and asystole.[Ref]

Cardiac arrhythmias, especially increased ventricular ectopy, have been associated with PEG-ELS use.

The manufacturer notes an isolated case of asystole following ingestion of PEG-ELS in a geriatric patient (equal to or greater than 60 years of age).[Ref]

Hypersensitivity

Hypersensitivity side effects with PEG-ELS have rarely included anaphylaxis.[Ref]

A 70-year-old male developed shortness of breath, wheezing, skin flushing, and lowered blood pressure after drinking a second glass of PEG-ELS.[Ref]

Other

Other side effects with PEG-ELS have included rhinorrhea.[Ref]

Respiratory

Respiratory side effects with PEG-ELS have included sudden dyspnea with pulmonary edema, and 'butterfly-like' infiltrate on chest X-ray.[Ref]

The manufacturer notes isolated reports of 'butterfly-like' infiltrate on chest X-ray following vomiting and aspiration of PEG-ELS and sudden dyspnea with pulmonary edema in geriatric patients (equal to or greater than 60-years-old). [Ref]

Nervous system

Nervous system side effects have included tonic-clonic seizures.[Ref]

Tonic-clonic seizures have been reported in patients with and without previous history of seizures following administration of PEG-ELS (4 liters).

Rivaroxaban Side Effects

Warning

Oral route (Tablet)

Premature discontinuation of any oral anticoagulant, including rivaroxaban, increases the risk of thrombotic events. To reduce this risk, consider coverage with another anticoagulant if rivaroxaban is discontinued for a reason other than pathological bleeding or completion of a course of therapy. Epidural or spinal hematomas, which may result in long-term or permanent paralysis, have occurred in patients treated with rivaroxaban who are receiving neuraxial anesthesia or undergoing spinal puncture. Optimal timing between the

administration of rivaroxaban and neuraxial procedures is not known. Factors that can increase the risk of developing hematomas include: use of indwelling epidural catheters; concomitant use of drugs affecting hemostasis, such as NSAIDs, platelet inhibitors, or other anticoagulants; or a history of traumatic or repeated epidural or spinal punctures, spinal deformity, or spinal surgery. Monitor patients frequently for neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider risks/benefits before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.

Serious side effects of Rivaroxaban

Along with its needed effects, rivaroxaban may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking rivaroxaban:

More common

- Back pain
- bleeding gums
- bloody stools
- bowel or bladder dysfunction
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- coughing up blood
- difficulty with breathing or swallowing
- dizziness
- headache
- increased menstrual flow or vaginal bleeding
- leg weakness
- nosebleeds
- numbness
- paralysis
- prolonged bleeding from cuts
- red or black, tarry stools
- red or dark brown urine
- vomiting of blood or material that looks like coffee grounds

Less common

- Fainting

- pain in the arms or legs
- wound secretion

Rare

- Burning feeling while urinating
- difficult or painful urination

Incidence not known

- Blistering, peeling, or loosening of the skin
- blurred vision
- chest tightness
- chills
- clay-colored stools
- cough
- dark urine
- diarrhea
- fast or irregular heartbeat
- fever with or without chills
- general feeling of tiredness or weakness
- hives, itching, skin rash
- hoarseness
- joint or muscle pain
- loss of appetite
- lower back or side pain
- nausea
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- red skin lesions, often with a purple center
- red, irritated eyes
- severe headache
- sore throat
- sores, ulcers, or white spots in the mouth or on the lips
- stomach pain or swelling
- unpleasant breath odor
- unusual bleeding or bruising
- unusual tiredness or weakness
- vomiting
- yellow eyes or skin

Other side effects of Rivaroxaban

Some side effects of rivaroxaban may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

Less common

- Blisters
- muscle spasm

For Healthcare Professionals

Applies to rivaroxaban: **oral granule for reconstitution, oral kit, oral tablet**.

General

The most common adverse reactions were bleedings/bleeding complications/bleeding events.[Ref]

Cardiovascular

Common (1% to 10%): Hypotension, hematoma, hypertension, tachycardia, procedural hypotension, deep vein thrombosis

Uncommon (0.1% to 1%): Traumatic hematoma

Rare (0.01% to 0.1%): Vascular pseudoaneurysm

Frequency not reported: Hypoperfusion, cardiac ischemia symptoms (e.g., chest pain, angina pectoris), decreased blood pressure[Ref]

Dermatologic

Common (1% to 10%): Pruritus, rash, ecchymosis, cutaneous hemorrhage, subcutaneous hemorrhage, blister, unspecific blistering, subcutaneous hematoma

Uncommon (0.1% to 1%): Generalized pruritus, angioedema, allergic dermatitis, urticaria, ecchymosis, skin hemorrhage, drug eruption, pruritic rash, erythematous rash, generalized rash

Very rare (less than 0.01%): Toxic epidermal necrolysis

Frequency not reported: Generalized urticaria, maculopapular rash, viral rash

Postmarketing reports: Stevens-Johnson syndrome, drug reaction with eosinophilia and systemic symptoms (DRESS), angioedema[Ref]

Gastrointestinal

Very common (10% or more): Nausea (up to 11.1%)

Common (1% to 10%): Gingival bleeding, gastrointestinal (GI) tract hemorrhage, rectal hemorrhage, GI pain, abdominal pain, dyspepsia, constipation, diarrhea, vomiting, upper abdominal pain, major GI bleeding, GI bleeding events (included upper GI bleeding, lower GI bleeding, rectal bleeding), GI hemorrhage

Uncommon (0.1% to 1%): Dry mouth, increased lipase, increased amylase, anal hemorrhage, hematemesis, hematochezia, hemorrhoidal hemorrhage, lower GI hemorrhage, melena, lip hemorrhage, mouth hemorrhage, tongue hemorrhage, abdominal discomfort, lower abdominal pain, occult blood positive, upper GI hemorrhage, gastric ulcer hemorrhage, hemorrhagic gastritis, gastric hemorrhage

Rare (0.01% to 0.1%): Nonfatal retroperitoneal bleeding

Frequency not reported: Gastroenteritis (including viral gastroenteritis), stomach discomfort, epigastric discomfort[Ref]

Genitourinary

Common (1% to 10%): Urogenital tract hemorrhage, hematuria, menorrhagia, urinary tract infection, urinary retention, vaginal hemorrhage

Uncommon (0.1% to 1%): Metrorrhagia, blood urine present

Rare (0.01% to 0.1%): Menometrorrhagia

Frequency not reported: Abnormal vaginal/increased menstrual bleeding[Ref]

Hematologic

Very common (10% or more): Any bleeding (up to 28.3%)

Common (1% to 10%): Anemia (including respective laboratory parameters), postprocedural hemorrhage (including postoperative anemia, wound hemorrhage), hemorrhage, thrombocytosis, major bleeding, clinically relevant nonmajor bleeding, modified International Society on Thrombosis and Hemostasis (ISTH) major bleeding, bleeding leading to hospitalization (nonfatal, noncritical organ, not requiring reoperation), Thrombolysis in Myocardial Infarction Bleeding Criteria (TIMI) major bleeding (coronary artery bypass graft

[CABG]/non-CABG), clinically overt signs of hemorrhage associated with a drop in hemoglobin (Hb) of at least 5 g/dL or drop in hematocrit of at least 15%

Uncommon (0.1% to 1%): Increased platelet count, operative hemorrhage, traumatic hemorrhage, decreased Hb, decreased hematocrit, bleeding varicose vein, nonfatal symptomatic bleeding in critical organ, decrease in Hb of at least 2 g/dL, nonfatal noncritical organ bleeding, transfusion of at least 2 units of packed RBCs/whole blood, nonfatal critical organ bleeding, bleeding that required reoperation, extra-surgical site bleeding requiring transfusion of more than 2 units of whole blood/packed cells, critical site bleeding, bleeding into a critical organ, fatal bleeding event

Rare (0.01% to 0.1%): Bleeding into the surgical site requiring reoperation (nonfatal noncritical organ), fatal non-intracranial bleeding

Frequency not reported: Trivial bleeding

Postmarketing reports: Agranulocytosis, thrombocytopenia[Ref]

Major bleeding was defined as clinically overt bleeding associated with a decrease in Hb of at least 2 g/dL, a transfusion of at least 2 units of packed RBCs/whole blood, bleeding at a critical site, or with a fatal outcome.

Clinically relevant nonmajor bleeding was bleeding that was clinically overt, did not meet the criteria for major bleeding, but was associated with medical intervention, unscheduled contact with physician, temporary cessation of therapy, discomfort for patient, or impairment of daily life activities.

Modified ISTH major bleeding was defined as fatal bleeding; symptomatic bleeding in a critical area or organ (e.g., intraarticular, IM with compartment syndrome, intraspinal, intracranial, intraocular, respiratory, pericardial, liver, pancreas, retroperitoneal, adrenal gland, kidney); bleeding into the surgical site requiring reoperation; or bleeding leading to hospitalization.

Nonfatal noncritical organ bleeding was major bleeding that was not fatal or in a critical organ, but resulted in a decrease in Hb of at least 2 g/dL and/or transfusion of at least 2 units of packed RBCs/whole blood.

Fatal bleeding was adjudicated death with the primary cause of death from bleeding[Ref]

Hepatic

Common (1% to 10%): Increased transaminases (including increased ALT, increased AST), increased GGT, increased ALT

Uncommon (0.1% to 1%): Hepatic impairment, increased bilirubin, increased AST, abnormal liver function test, increased hepatic enzyme, increased

conjugated bilirubin (with or without concomitant increase of ALT), hyperbilirubinemia

Postmarketing reports: Jaundice, cholestasis, hepatitis (including hepatocellular injury)[Ref]

Hypersensitivity

Uncommon (0.1% to 1%): Allergic reaction

Postmarketing reports: Hypersensitivity, anaphylactic reaction, anaphylactic shock, allergic edema[Ref]

Metabolic

Uncommon (0.1% to 1%): Hyperglycemia[Ref]

Musculoskeletal

Common (1% to 10%): Pain in extremity, contusion, back pain, muscle spasm, arthralgia, increased muscle cramping

Uncommon (0.1% to 1%): Hemarthrosis

Rare (0.01% to 0.1%): Muscle hemorrhage

Frequency not reported: Compartment syndrome (secondary to bleeding)[Ref]

Nervous system

Common (1% to 10%): Dizziness, headache, syncope, increased muscle tone

Uncommon (0.1% to 1%): Cerebral hemorrhage, loss of consciousness, intracranial hemorrhage/bleeding, nonfatal intracranial hemorrhage/bleeding, hemorrhagic stroke (fatal and nonfatal), other intracranial hemorrhage/bleeding (fatal and nonfatal), fatal intracranial hemorrhage/bleeding

Rare (0.01% to 0.1%): Subdural hematoma, cerebellar hemorrhage, hemorrhagic transformation stroke

Postmarketing reports: Hemiparesis[Ref]

Intracranial bleeding events included intraparenchymal, intraventricular, subdural, subarachnoid, and/or epidural hematoma. Hemorrhagic stroke referred to nontraumatic intraparenchymal and/or intraventricular hematoma in patients on therapy plus 2 days.[Ref]

Ocular

Common (1% to 10%): Eye hemorrhage, conjunctival hemorrhage

Uncommon (0.1% to 1%): Vitreous hemorrhage, periorbital hematoma

Rare (0.01% to 0.1%): Nonfatal intraocular bleeding[Ref]

Other

Common (1% to 10%): Pyrexia/fever, peripheral edema, decreased general strength and energy, fatigue, asthenia, wound secretion, unspecific pain, wound healing complications, feeling unwell, wound hemorrhage

Uncommon (0.1% to 1%): Increased blood alkaline phosphatase, malaise, increased lactate dehydrogenase, incision site hemorrhage

Rare (0.01% to 0.1%): Localized edema, feeling abnormal

Frequency not reported: Mucosal bleedings (i.e., epistaxis, gingival, gastrointestinal, genitourinary [including abnormal vaginal/increased menstrual bleeding])[Ref]

Psychiatric

Common (1% to 10%): Insomnia, anxiety, depression, sleep disorders[Ref]

Renal

Common (1% to 10%): Renal impairment (including increased blood creatinine, increased blood urea)

Uncommon (0.1% to 1%): Decreased renal CrCl, increased blood creatinine, increased blood urea

Frequency not reported: Renal failure/acute renal failure (secondary to bleeding sufficient to cause hypoperfusion)

Postmarketing reports: Anticoagulant-related nephropathy[Ref]

Respiratory

Common (1% to 10%): Epistaxis/nosebleed, hemoptysis, dyspnea

Very rare (less than 0.01%): Eosinophilic pneumonia

Frequency not reported: Pulmonary hemorrhage, pulmonary hemorrhage with bronchiectasis, epistaxis leading to transfusion, cough

Postmarketing reports: Eosinophilic pneumonia[Ref]

Trazodone Side Effects

Warning

Oral route (Tablet, Extended Release; Tablet)

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior in children, adolescents, and young adults with major depressive disorder (MDD) and other psychiatric disorders in short-term studies. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared with placebo in adults beyond age 24, and there was a reduction in risk with antidepressants compared with placebo in adults aged 65 or older. The use of trazodone hydrochloride or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Closely monitor patients of all ages for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Not approved for pediatric use.

Serious side effects of Trazodone

Along with its needed effects, trazodone may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking trazodone:

More common

- Blurred vision
- confusion
- dizziness
- dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- lightheadedness
- sweating
- unusual tiredness or weakness

Less common

- Burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- confusion about identity, place, and time

- decreased concentration
- fainting
- general feeling of discomfort or illness
- headache
- lack of coordination
- muscle tremors
- nervousness
- pounding in the ears
- shortness of breath
- slow or fast heartbeat
- swelling

Rare

- Skin rash
- unusual excitement

Other side effects of Trazodone

Some side effects of trazodone may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

More common

- Dry mouth (usually mild)
- muscle or bone pain
- trouble sleeping
- trouble with remembering
- unpleasant taste

Less common

- Constipation
- continuing ringing or buzzing or other unexplained noise in the ears
- diarrhea
- hearing loss
- muscle aches or pains
- weight loss

For Healthcare Professionals

Applies to trazodone: **compounding powder, oral tablet, oral tablet extended release**.

General

The most commonly reported side effects included drowsiness, dry mouth, dizziness, and lightheadedness.[Ref]

Nervous system

Drowsiness has occurred during the first few days of treatment, and usually disappeared with continue administration.[Ref]

Very common (10% or more): Drowsiness (up to 41%), dizziness (up to 28%), lightheadedness (up to 28%), headache (up to 20%)

Common (1% to 10%): Decreased concentration, head full-heavy, incoordination, syncope, tremor

Frequency not reported: Akathisia, altered taste, convulsion, decreased alertness, dystonia, expressive aphasia, impaired memory, impaired speech, memory disturbance, motor impairment, neuroleptic malignant syndrome, numbness, paresthesia, serotonin syndrome, vertigo

Postmarketing reports: Aphasia, ataxia, cerebrovascular accident, extrapyramidal symptoms, grand mal seizures, stupor, tardive dyskinesia[Ref]

Gastrointestinal

Very common (10% or more): Dry mouth (up to 34%), nausea (up to 13%), vomiting (up to 13%)

Common (1% to 10%): Abdominal disorder, constipation, diarrhea, gastric disorder

Frequency not reported: Dyspepsia, flatulence, gastroenteritis, hypersalivation, increased salivation, paralytic ileus, stomach pain

Postmarketing reports: Increased amylase[Ref]

Cardiovascular

Very common (10% or more): Hypertension (up to 20%)

Common (1% to 10%): Edema, hypotension

Frequency not reported: Bradycardia, cardiac arrhythmias, chest pain, ECG abnormalities, increased risk of bleeding, orthostatic hypotension, palpitations, premature ventricular beats, QT prolongation, sinus bradycardia, tachycardia, Torsade de pointes, ventricular couplets, ventricular tachycardia

Postmarketing reports: Atrial fibrillation, cardiac arrest, cardiospasm, conduction block, congestive heart failure, myocardial infarction, vasodilation, ventricular ectopic activity[Ref]

QT prolongation, Torsade de pointes, and ventricular tachycardia have been reported in patients with doses up to 100 mg/day.[Ref]

Ocular

Very common (10% or more): Blurred vision (up to 15%)

Common (1% to 10%): Itching eyes, red eyes, tired eyes

Frequency not reported: Angle-closure glaucoma, myoclonus

Postmarketing reports: Diplopia[Ref]

Psychiatric

Very common (10% or more): Nervousness (up to 15%)

Common (1% to 10%): Confusion

Frequency not reported: Activation of mania/hypomania, aggressive reaction, agitation (sometimes exacerbating to delirium), anxiety, cognitive impairment, confusional state, delusions, discontinuation syndrome, hallucinations, hypomania, increased libido, insomnia, libido decreased, mania, nightmares, restlessness, suicidal behavior, suicidal ideation, suicidal thoughts, withdrawal syndrome

Postmarketing reports: Abnormal dreams, paranoid reaction, psychoses[Ref]

Other

Very common (10% or more): Fatigue (up to 11%)

Common (1% to 10%): Aches, malaise, pain

Frequency not reported: Fever, weakness

Postmarketing reports: Chills, unexplained death[Ref]

Metabolic

Common (1% to 10%): Weight gain, weight loss

Frequency not reported: Anorexia, hyponatremia, increased appetite[Ref]

Respiratory

Common (1% to 10%): Nasal congestion, sinus congestion

Frequency not reported: Dyspnea, shortness of breath

Postmarketing reports: Apnea[Ref]

Dermatologic

Common (1% to 10%): Skin condition

Frequency not reported: Hyperhidrosis, pruritus, skin rash

Postmarketing reports: Alopecia, hirsutism, leuconychia, psoriasis, urticaria[Ref]

Genitourinary

Frequency not reported: Delayed urine flow, early menses, hematuria, impotence, increased urinary frequency, micturition disorders, missed periods, priapism, retrograde ejaculation

Postmarketing reports: Breast engorgement, breast enlargement, clitorism, lactation, urinary incontinence, urinary retention[Ref]

Hepatic

Frequency not reported: Cholestasis intrahepatic, elevated liver enzymes, fulminant hepatitis, hepatic failure with potentially fatal outcome, hepatic function abnormalities, hepatitis, hepatocellular damage, jaundice, severe hepatic disorders

Postmarketing reports: Cholestasis, hyperbilirubinemia, liver enzyme alterations[Ref]

Hematologic

Frequency not reported: Agranulocytosis, anemia, blood dyscrasias, eosinophilia, leukopenia, thrombocytopenia

Postmarketing reports: Hemolytic anemia, leukocytosis, methemoglobinemia[Ref]

Musculoskeletal

Frequency not reported: Arthralgia, back pain, limb pain, muscle twitches, myalgia[Ref]

Hypersensitivity

Frequency not reported: Allergic reactions[Ref]

Immunologic

Frequency not reported: Influenza-like symptoms[Ref]

Endocrine

Frequency not reported: Syndrome of inappropriate antidiuretic hormone (SIADH) secretion[Ref]

Zinc sulfate side effects

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

Other side effects of Zinc sulfate

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if you have any side effects that bother you or do not go away.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

For Healthcare Professionals

Applies to zinc sulfate: **compounding powder, intravenous solution, oral capsule, oral tablet**.

Gastrointestinal

Gastrointestinal side effects of zinc sulfate when taken in large doses have included diarrhea, abdominal cramps, and vomiting, usually within 3 to 10 hours of dosing. The symptoms go away soon after discontinuation.[Ref]

Respiratory

Respiratory side effects have included losing sense of smell in patients who use nasal sprays containing zinc